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Remedium Group, Inc.

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Parametrix



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TABLE OF CONTENTS

INTRODUCTION	XI
1. MANAGEMENT AND ORGANIZATION	1-1
1.1 QUALITY MANAGEMENT PHILOSOPHY	1-1
1.2 ORGANIZATION AND MANAGEMENT	1-1
1.2.1 Parametrix Organization	1-1
1.2.2 Project and Work Order Management Staff	1-3
1.2.3 Subcontractor QA Requirements	1-3
1.3 QUALITY MANAGEMENT RESPONSIBILITIES/AUTHORITIES	1-4
1.3.1 Parametrix QA Officer	1-4
1.3.2 Parametrix Contract Management Staff	1-4
1.3.3 Work Order QA Managers	1-5
1.3.4 Subcontractor QA Managers	1-5
1.3.5 Analytical Services Coordinator	1-6
2. QUALITY SYSTEM DESCRIPTION	2-1
2.1 WORK ORDER LEVEL	2-1
2.2 INTERFACES BETWEEN THE COMPANY AND WORK ORDER LEVELS	2-1
3. PLANNING	3-1
3.1 IDENTIFYING REQUIREMENTS	3-1
3.2 MEETING THE REQUIREMENTS	3-1
3.3 PLANNING DOCUMENTS	3-2
3.3.1 Work Order Work Plan	3-2
3.3.2 QAPP	3-3
3.3.3 Health and Safety Plans (HSPs)	3-3
4. PERSONNEL QUALIFICATION AND TRAINING	4-1
4.1 TRAINING AND QUALITY	4-1
4.2 TRAINING NEEDS ASSESSMENT AND IMPLEMENTATION	4-1
4.3 TRAINING DOCUMENTATION	4-2
5. PROCUREMENT OF ITEMS AND SERVICES	5-1
5.1 PROCUREMENT OF ITEMS	5-1
5.2 PROCUREMENT OF SERVICES	5-1
6. DOCUMENTS AND RECORDS	6-1
6.1 DOCUMENT CONTROL	6-1
6.1.1 Technical Review	6-1
6.1.2 Quality Assurance Review	6-1
6.2 RECORDS CONTROL	6-1
6.2.1 Custody Requirements for Project Documents	6-2

TABLE OF CONTENTS (CONTINUED)

6.2.2 Treatment of Confidential Business Information	6-2
7. COMPUTER HARDWARE AND SOFTWARE	7-1
7.1 COMMERCIALLY AVAILABLE HARDWARE AND SOFTWARE	7-1
7.2 SOFTWARE DEVELOPMENT	7-1
8. IMPLEMENTATION OF WORK ORDER PROCESSES	8-1
8.1 STAFF QUALIFICATIONS	8-1
8.2 PLANS AND PROCEDURES	8-1
8.3 WORK ORDER START-UP	8-2
8.4 FIELD PLANNING MEETINGS	8-2
8.5 CONTROL OF ITEMS AFFECTING QUALITY	8-2
8.5.1 Inspection and Testing	8-2
8.5.2 Samples and Sample Custody	8-3
8.5.3 Measurement and Test Equipment	8-3
8.5.4 Nonconforming Items	8-3
8.6 SUPERVISION AND OVERSIGHT	8-3
8.6.1 Supervision of Work Order	8-4
8.6.2 Oversight of Work Order	8-4
8.7 CONTROL OF SPECIAL PROCESSES	8-4
9. ASSESSMENTS AND RESPONSES	9-1
9.1 MANAGEMENT ASSESSMENTS	9-1
9.1.1 Management Self-Assessment	9-1
9.1.2 Independent Management Assessments	9-2
9.2 TECHNICAL ASSESSMENTS	9-2
9.2.1 Technical Self-Assessments	9-2
9.2.2 Technical Independent Assessments	9-4
9.3 FREQUENCY OF INDEPENDENT ASSESSMENTS	9-6
9.4 RESPONSE TO ASSESSMENTS	9-7
9.4.1 Purpose of Assessments	9-7
9.4.2 Responses to Different Types of Assessments	9-7
9.5 CORRECTIVE ACTION SYSTEM	9-8
9.5.1 Organizational Corrective Action	9-9
10. QUALITY IMPROVEMENT	10-1
10.1 INDIVIDUAL RESPONSIBILITY	10-1
10.2 NO-FAULT ATTITUDE	10-1
10.3 IDENTIFYING IMPROVEMENT OPPORTUNITIES	10-1
10.3.1 Employee Level	10-1

TABLE OF CONTENTS (CONTINUED)

10.3.2 Contract and Work Order Level	10-1
10.3.3 Corporate Level	10-2
10.4 IMPLEMENTING IMPROVEMENTS.....	10-2

LIST OF FIGURES

1-1 Contract Organization.....	1-2
--------------------------------	-----

LIST OF TABLES

9-1 Assessment Frequency.....	9-6
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APPENDICES

- A Quality Assurance Project Plan for Remedium Work Orders
- B Analytical Services Plan

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ACRONYMS AND ABBREVIATIONS

ASP	Analytical Services Plan
CAR	Corrective Action Request
CBI	Confidential Business Information
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CHSO	Corporate Health and Safety Officer
CO	Contracting Officer
COO	Chief Operations Officer
CQO	Corporate Quality Officer
DQAs	Data Quality Assessments
DQOs	Data Quality Objectives
EPA	U.S. Environmental Protection Agency
HSP	Health and Safety Plan
M&TE	Measurement and Test Equipment
PE	Performance Evaluation
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QP	Quality Procedure
SOPs	Standard Operating Procedures
SOW	Statement of Work
WBS	Work Breakdown Structure

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INTRODUCTION

Under the direction of the Corporate Quality Officer (CQO), Parametrix has prepared this Quality Management Plan (QMP) to support our work at the Libby Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) site, hereafter referred to the more common name of Libby Superfund site. The QMP reflects Parametrix's commitment to quality and is the blueprint for our quality program. This document describes or references the controls, quality procedures, and guidelines to be followed for work performed by Parametrix and its subcontractors under contract with Remedium Group, Inc. (Remedium).

This QMP has been developed in accordance with the specific requirements of the U.S. Environmental Protection Agency (EPA) QA/R-2, EPA Requirements for Quality Management Plans. Part I of this QMP provides an overview of the quality assurance (QA) program. Within each section, as appropriate, references are made to Quality Procedures (QPs) which are located in Part II. QPs provide detailed instructions, responsibilities, and documentation requirements necessary to ensure the effective implementation of the quality program elements. A generic contract Quality Assurance Project Plan (QAPP) is contained in Appendix A. A generic Analytical Services Plan (ASP) for our work with Remedium is provided in Appendix B.

The QMP plan is revision-controlled. The header at the top of each page lists the revision number; the footer at the bottom of each page lists the date. This QMP will be revised, as required, based on:

- Revised contract and/or Parametrix requirements.
- Revision of the Parametrix Corporate QMP (every five years minimum).
- Recommendations during the annual review of this QMP.

Each revision will include instructions. It is the QMP owner's responsibility to update the plan promptly. Throughout this document, the following meanings apply:

- *Will, shall, and must* indicate the element is required.
- *Should* indicates the element is recommended.
- *May* indicates the element is optional or discretionary.

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1. MANAGEMENT AND ORGANIZATION

1.1 QUALITY MANAGEMENT PHILOSOPHY

The management philosophy of Parametrix includes:

- Client satisfaction.
- Full commitment to quality by top management.
- Involvement of all employees.
- Teamwork between all employees.
- Continuous improvement of work products and services.

Quality is every employee's responsibility, a fact succinctly stated in the Parametrix Vision Statement for the corporation: 'Our work is conducted without compromise to the quality of our science or design.' This is the standard to which we must always hold ourselves accountable as engaged employee owners.

1.2 ORGANIZATION AND MANAGEMENT

1.2.1 Parametrix Organization

The Parametrix contract organization is shown in Figure 1-1. The Parametrix Quality Assurance (QA) Officer (hereafter referred to as the "QA Officer") is responsible for overall quality management. The QA Officer reports directly to the Parametrix Chief Operations Officer (COO). The Principal-in-Charge is always available as a senior Parametrix executive regarding matters of QA and QA implementation, as well as any other contract issues.

Throughout the contract, the Parametrix QA Officer, Parametrix Work Order QA Managers, and Subcontractor QA Managers will communicate regularly on all QA/QC requirements. Specifically, the Parametrix QA Officer and Work Order QA Managers will work closely with Subcontractor QA Managers to ensure that any QA concerns are communicated, addressed, and resolved.

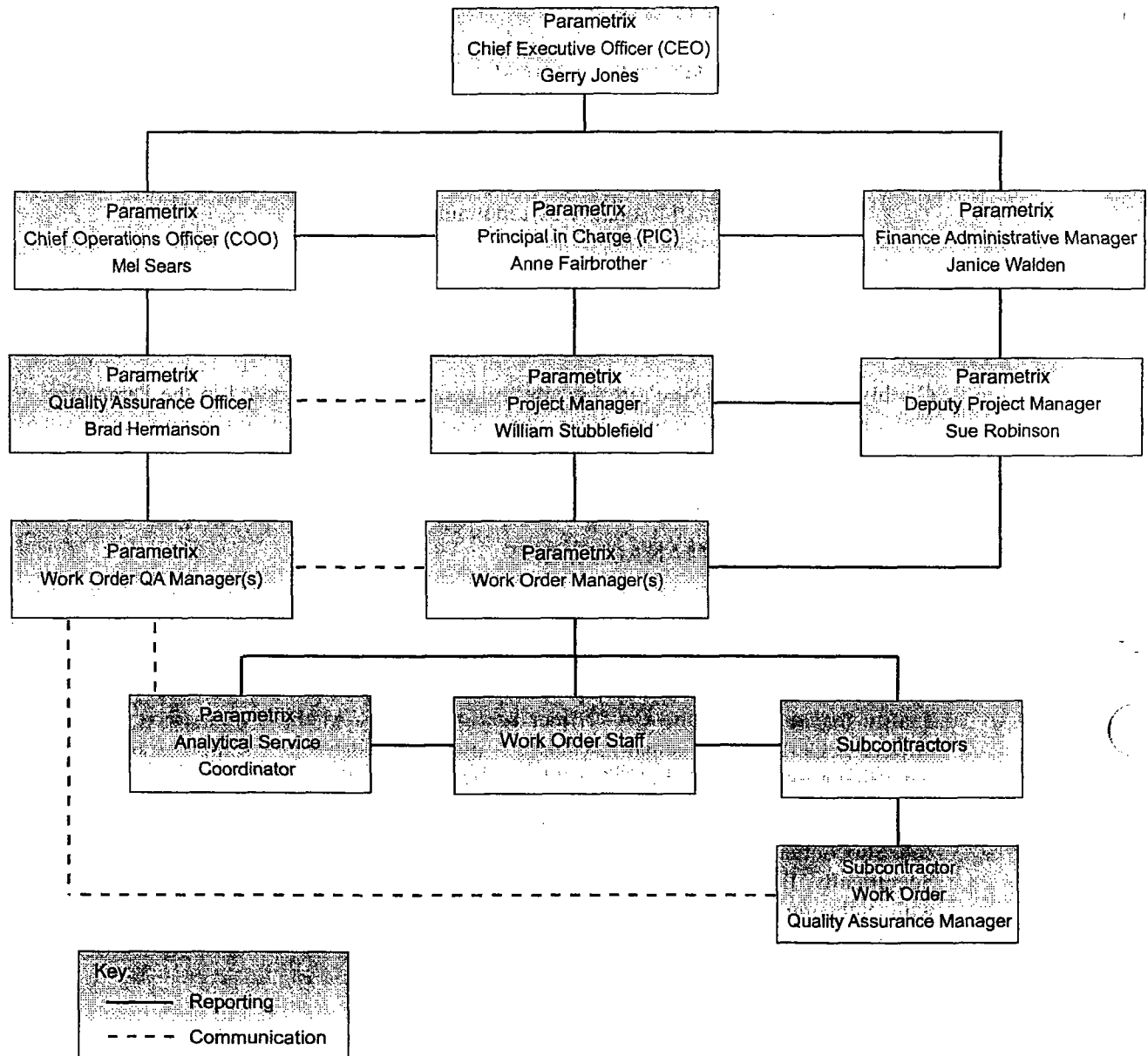


Figure 1-1. Contract Organization

1.2.2 Project and Work Order Management Staff

The Parametrix Project Manager (hereafter referred to as the "Project Manager"), Work Order Managers, and other supervisory staff are responsible for ensuring that relevant quality procedures are implemented by themselves and their staff. Specific responsibilities include:

- Ensuring that their staff members know the quality and technical requirements for each work order.
- Ensuring that adequate resources to meet the contract quality requirements are included in work order budgets.
- Consulting with the assigned QA staff regarding quality requirements.
- Ensuring that QA sections are prepared for work order work plans and data reports.
- Ensuring that technical and quality assurance review procedures are implemented.
- Ensuring that QA review requirements are met.
- Scheduling and conducting self-assessments.
- Cooperating during internal and external QA audits.
- Performing subcontract management and oversight.
- Reporting regularly to the Parametrix Principal-in-Charge.

1.2.3 Subcontractor QA Requirements

1.2.3.1 Parametrix Subcontractors

Parametrix will require from all Team Subcontractors:

- A commitment to implement the Parametrix QA program described in the contract QMP and/or QAPPs as it applies to their firm's contract work.
- A Subcontract QA Manager and Work Order QA Managers (as necessary).
- The submission of QA/QC procedures and/or Standard Operating Procedures (SOPs) that are specific to the types of technical work anticipated under the subcontract and not otherwise included in the work order QAPP.
- Implementation of an internal corrective action system.
- Agreement to corrective actions required by Parametrix.
- Implementation of a documented technical review system.
- Regular QA summary reports to the Parametrix QA Officer.

1.2.3.2 Other Subcontractors

QA/QC requirements for other subcontractors will vary depending on the technical work and requirements for individual work orders. Therefore, QA/QC requirements will be written into individual subcontract documents. The appropriate elements from the list in Section 1.2.3.1 will be included.

1.3 QUALITY MANAGEMENT RESPONSIBILITIES/AUTHORITIES

1.3.1 Parametrix QA Officer

The QA Officer is responsible for developing, implementing, and assessing the implementation of the Parametrix quality program. The QA Officer is independent of the contract technical and management staff and has full access to and reports to the Parametrix COO. The QA Officer thus has the authority to review and identify problems and to bring corporate resources to bear in solving problems. If disputes arise with respect to quality matters, the QA Officer, in consultation with the COO, is the final arbitrator of the dispute.

1.3.2 Parametrix Contract Management Staff

The Project Manager, Deputy Project Manager, Work Order Managers, Work Order QA Managers, and other supervisory staff are responsible for ensuring that relevant quality procedures are implemented by themselves and their staff. They are supported by and have full access to Parametrix management in carrying out their responsibilities. Their specific responsibilities include:

- Ensuring that their staff members know the quality and technical requirements for each work order.
- Ensuring that adequate resources to meet contract quality requirements are included in work order budgets.
- Consulting with the assigned QA staff regarding quality requirements.
- Ensuring that QA sections are prepared for work plans and data reports.
- Ensuring that technical review procedures are implemented on all technical documents.
- Ensuring that QA review requirements are met.
- Scheduling and conducting self-assessments.
- Cooperating during internal and external QA audits.
- Suggesting improvements to quality systems, documents, and procedures.
- Devising corrective actions to resolve problems and ensuring completion of corrective actions.
- Regular communication with the QA Officer.
- Direct communication with the QA Officer if a quality-related concern is not adequately addressed through the normal administrative chain of command.
- Considering each employee's quality implementation during performance appraisals.

1.3.3 Work Order QA Managers

Work Order QA Managers are independent of the contract technical and management staff and report to the QA Officer. They have full authority to make quality-related decisions with respect to work orders. Specifically, this includes the authority to stop work if they identify issues or problems that may affect the quality of the work being performed, and to resolve quality issues through the normal administrative chain of command. Work Order QA Managers are further responsible for:

- Actively tracking the implementation of this QMP on specific work orders and consulting with Work Order Managers.
- Working with work order staff to select appropriate quality measures for their work.
- Interfacing with and providing oversight to Subcontractor QA Managers.
- Training technical staff in task-specific QA requirements.
- Reviewing work order QAPPs.
- Reviewing data reports for QA requirements.
- Conducting or arranging work-order-specific audits or surveillances as necessary.
- Initiating and following up on corrective action requests (CARs).
- Reporting regularly to Work Order Managers.

1.3.4 Subcontractor QA Managers

Each Subcontractor QA Manager also functions independently of his/her technical and management staff. Subcontractor QA Managers have full authority to make quality-related decisions with respect to their assigned work. This specifically includes the authority to stop work if they identify issues or problems that may affect the quality of the work being performed and to resolve quality issues through the normal administrative chain of command. In this regard, they have full access to and report to the Work Order QA Managers. They are also responsible for the following tasks within their firm:

- Requiring their staff to implement the contract QA program.
- Meeting the requirements of their contract assignment.
- Supporting any necessary corrective actions.
- Responsibilities identified in work-order-specific QAPPs.
- Regular reporting to the Work Order QA Manager.

Other responsibilities and roles associated with the contract are addressed in work orders or QAPPs.

1.3.5 Analytical Services Coordinator

The Analytical Services Coordinator or designee is assigned to all work orders requiring analytical laboratory services. The Analytical Services Coordinator shares certain responsibilities with the Work Order QA Managers, specifically those dealing with analytical services as follows:

- Acting as Parametrix's primary point of contact with subcontractor laboratories.
- Working with Work Order Managers and internal project staff to define appropriate QC requirements that will meet the data quality objectives (DQOs) for each work assignment.
- Reviewing all work order QAPPs.
- Assisting with the preparation, review, and approval of laboratory Statements of Work (SOWs) and procurement packages for subcontractor laboratories in accordance with the Analytical Services Plan (ASP).
- Scheduling sample receipts with subcontractor laboratories.
- Communicating with Work Order Managers and field staff to ensure that sample management and documentation requirements are being met during field operations.
- Submitting sample trip reports as necessary.
- Tracking all samples from time of scheduling to receipt of validated data by the project team.
- Ensuring that changes in procedures are communicated to project staff promptly.
- Conducting or arranging for subcontractor laboratory audits or surveillances, including laboratory performance evaluation (PE) samples.
- Overseeing and/or conducting data validation from subcontractor laboratories.

1.3.5.1 All Employees

All Parametrix employees are responsible for performing quality work that meets or exceeds Parametrix and applicable regulatory agency requirements. These requirements are defined during the quality planning described in Section 3.0 of this QMP. However, specific responsibilities include:

- Knowing the requirements for each work order effort.
- Using appropriate quality measures for each work order effort.
- Maintaining familiarity with the contract QMP and work order QAPPs.
- Suggesting modifications and improvements to quality systems, documents, and procedures.
- Notifying an immediate supervisor, QA Officer, Work Order QA Manager, Work Order Manager, Deputy Project Manager, or Project Manager of quality problems and proposing suggestions for solving them. Employees always have immediate access to supervisors and managers through personal contact, phone, fax, and e-mail and are encouraged to contact these individuals as necessary.

1.3.5.2 Policy on Waste, Fraud, and Abuse

All Parametrix employees and subcontractor employees are responsible to report any observed instances of fraud, waste, and abuse consistent with applicable guidance, such as EPA Manual 6500, "Functions and Activities of the Office of the Inspector General," January 22, 1985, and 40 CFR Part 3. Specifically, Parametrix and subcontractor employees are responsible for promptly reporting instances of, and information on, any known or suspected violation of law, rules, or regulations; mismanagement; gross waste of funds; abuse of authority; or substantial and specific danger to the public health and safety. Employees should report such instances to their supervisors, the Principal-in-Charge, or if necessary, the COO.

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2. QUALITY SYSTEM DESCRIPTION

The Parametrix quality program includes management controls at the contract level and at the work order level. Examples of each are noted below.

2.1 WORK ORDER LEVEL

The Work Order QA Manager implements the work order level quality system with assistance, guidance, review, and oversight by the Work Order Manager. This process includes input to or development of the following:

- Work Order DQOs.
- QAPPs and HSPs.
- Work Order Audits.
- Work Order Surveillances.

2.2 INTERFACES BETWEEN THE COMPANY AND WORK ORDER LEVELS

The following examples of interfaces demonstrate how quality system elements are communicated between the company and work order levels. This communication and integration serves to build in and verify quality for all work orders. All quality system requirements and elements in this QMP are communicated between the levels in similar fashion.

- Quality planning interfaces:
 - QA Officer and Project/Deputy Project Manager: Define quality requirements in the QMP and distribute it to the Work Order Managers.
 - Work Order Managers: Incorporate QMP requirements into work orders and QAPPs.
 - Work Order QA Managers: Review work plans and QAPPs and insert additional quality requirements into these plans as necessary.
 - Project Staff: Follows QMP, work plans, and QAPPs.
- Responsibilities of management and staff:
 - QA Officer:
 - Defines independent assessment requirements as necessary.
 - Ensures that independent assessments are conducted as necessary.
 - Work Order QA Managers:
 - Conducts or arranges independent assessments.
 - Reviews and issues independent assessment reports.
 - Project/Deputy Project Manager:
 - Defines self-assessment requirements.
 - Reviews and issues self-assessment reports.
 - Technical Staff: Conducts self-assessments as required.
 - Work Order Managers: Responds to assessments as necessary.
 - QA Officer: Evaluates and accepts responses to CARs.

3. PLANNING

Planning involves defining the scope of the work order, identifying requirements, and specifying ways to accomplish the requirements. Planning also provides Work Order Managers with the means to measure progress and control the work order work. There are three steps involved in planning: 1) Identify the requirements of the scope of work. 2) Determine in detail the practices, procedures, and steps to meet these requirements. 3) Document the requirements and practices, procedures, and steps in a planning document(s).

3.1 IDENTIFYING REQUIREMENTS

Not all work orders require the same level of quality control (QC) (i.e., the graded approach). The nature of the work order, the intended use of the data, and the budget determine the level of QC that is appropriate to that work order. Parametrix will develop the work order DQOs (if not already developed by involved regulatory agencies). DQOs are qualitative and quantitative statements developed by data users to specify the quality of the data needed from a particular data collection activity to support specific decisions or actions. DQOs will be developed according to EPA's *Data Quality Objectives Process*, EPA QA/G-4, Final, August 2000, and to provide data of known and appropriate quality for each work order. The DQO process is a seven-step planning approach to develop sampling designs for data collection activities that support decision making. It provides a systematic procedure for defining the criteria that a data collection design should satisfy including: when to collect samples, where to collect samples, the tolerable level of decision errors for the study, and how many samples to collect. Additional information on implementation of the DQO process can be found in Appendix A, Quality Assurance Project Plan.

Overall, the Work Order Manager, working with the technical staff, is ultimately responsible for determining the technical and quality objectives through:

- Broad-based communication with Remedium and involved regulatory agencies, *EPA's Guidance on Systematic Planning Using the Data Quality Objective Process*, EPA QA/G-4 2006.
- Knowledge of similar work orders.
- Best professional judgment.

3.2 MEETING THE REQUIREMENTS

Once the requirements are determined, the Work Order Manager is responsible for using planning techniques to:

- Identify the critical elements of the work order and specify ways to address them.
- Determine data collection requirements and techniques.
- Specify procedures to accomplish the activities.
- Determine what quality procedures are necessary.
- Determine the appropriate qualifications for the staff working on the assignment.
- Determine training requirements for the staff.
- Establish quality requirements for subcontractors.

- Determine documentation requirements.
- Define equipment needs.
- Establish quality assessment types and tools to be used.
- Establish data review requirements.
- Determine the need for additional plans such as Health and Safety Plans (HSPs) or data management plans.

Planning techniques, based on the complexity and nature of the work order, may include:

- **Kickoff Meeting:** A meeting conducted at the initiation of a work order to discuss goals and objectives; the detailed work order scope, budget, schedule, scope responsibilities; and other work order execution details.
- **Team Meetings:** Routine meetings of key work order teams to interactively discuss program and work order QA issues.
- **Technical Advisory Groups:** Technical experts that meet at the request of the Project Manager to evaluate technical problems or risks and suggest solutions.

3.3 PLANNING DOCUMENTS

Planning documents are prepared to communicate work order requirements, procedures, and techniques to all project participants.

3.3.1 Work Order Work Plan

A work order work plan may be required on some or all work orders. If required by the Project Manager, the plan is written to document an understanding of work order requirements and how they will be met. When required, the work plan will generally include the following sections, as applicable:

- **Introduction:** Including background information and a synopsis of the work order.
- **Scope of Work:** Including a work breakdown structure (WBS) identifying work tasks, subtasks, and deliverables.
- **Work Schedule:** Tied to the WBS.
- **Staffing and Organization Plan.**
- **Budgets.**
- **Change Control Plan** (scope, schedule, budget).
- **Quality Plan or QAPP** (if applicable).
- **HSP.**
- **Communication Plan.**
- **Procurement Plan.**
- **Subcontract Management Plan.**

The Work Order Manager submits the work order work plan for technical review (QP 3.2), QA review (QP 3.3), and then for approval by the Project Manager. When approved, the work order work plan is the primary controlling document on the work order. If a modification to the work order work plan is required, it is done in accordance with the change control procedures and reviewed and approved in the same manner as the original document. The approved work order work plan is distributed to all project staff and implemented by the Work Order Managers as the guiding plan for the technical and quality requirements for the work order.

3.3.2 QAPP

Approved QAPPs are required for all environmental data collection activities. Environmental data are defined as any measurements that describe environmental processes or conditions, or the performance of environmental technology. This includes, but is not limited to, sample collection, acceptance of split samples, field measurements, geotechnical tests, or laboratory work.

QAPPs are written to plan and communicate the activities and the sequence required to successfully complete all work involving measurement and monitoring. The Work Order QA Manager works with project personnel and the Analytical Services Coordinator to define or implement already defined DQOs and to specify all appropriate QC measures. The technical SOPs that will be used in the performance of the work order must be identified in the QAPP and should be included with the document.

QAPPs require technical review by approved technical reviewers according to QP 3.2 and a QA review by an appointed QA Reviewer. Approval signatures by the Work Order Manager, Analytical Services Coordinator, and Work Order QA Manager are required before QAPPs are submitted. The QAPP must be approved by the appropriate regulatory agency with project oversight prior to the start of field work. The only exception to these approval steps will be for emergency response actions. An emergency response action is defined as one where the response contractor must mobilize to the site in less than 14 days after being notified that they need to conduct an emergency response activity. In this instance, however, oversight regulatory agency staff need to be notified that sampling activity may occur, and that the QAPP will follow within 30 days of the project start. Once submitted, any revisions that change the technical content of a QAPP are required to have the same reviews and approvals as the original document. The Work Order QA Managers implement QAPP requirements.

The QAPP is required reading for all field personnel. It is the primary communication tool between the work order planners and field personnel. The QAPP must be accessible on site during all field work. Any significant deviations from the QAPP must be documented for inclusion in the project report. This may be accomplished by documenting each deviation in the field logbook or on a field change notice. The impact of each significant deviation on the data should be assessed and documented in the project report.

3.3.3 Health and Safety Plans (HSPs)

Site-specific HSPs must be generated for activities performed at hazardous or potentially hazardous waste sites. The complexity of each individual plan will vary as to the types of operation and the physical and chemical exposure hazard potential associated with each site. The HSP is based on the Parametrix corporate Health and Safety Program requirements and serves as a vehicle for providing health and safety information to all individuals assigned to site activities and as such, will be available on site and reviewed by each employee before

performing site activities. In general, the HSP will be prepared, as a minimum, in accordance with the requirements of 29 CFR 1910.120.

Pertinent reasons for the generation of the HSP are as follows:

- To establish policies and procedures to protect employees and the public from site-specific health and safety hazard potentials.
- To provide measures to minimize/eliminate accidents and injuries that may result from chemical and physical hazards associated with the site.
- To ensure that all aspects of site operations have been carefully considered prior to initiation of any site tasks.
- To provide a mechanism to notify site employees of the chemical and physical hazard potentials that exist at the site, how those hazards can impact their health and well-being, and to prescribe personal protection and procedures required to minimize those hazards.
- To ensure that all potential contingencies have been thoroughly examined in advance of injuries, illnesses, fires, or other catastrophic events.

HSPs are reviewed and approved by the Parametrix Corporate Health and Safety Officer (CHSO) and implemented on the work order by the Work Order Manager with (as applicable) the Work Order Health and Safety Coordinator.

4. PERSONNEL QUALIFICATION AND TRAINING

4.1 TRAINING AND QUALITY

Quality work can only be expected from employees when they are thoroughly trained and understand the technical and contract-specific requirements of their work. As a matter of policy, all Parametrix and subcontractor staff will be qualified and trained to perform their assignments properly and safely. These qualifications may be met by combinations of education, experience, and specific training. Employees are hired based on their qualifications and abilities, but certain work orders may require additional training. Categories of training include:

- Project Management.
- Quality Assurance.
- Health and Safety.
- Technical Skills.
- Work-Order-Specific.

Work Order Managers receive initial project management training and regular training updates as part of the Parametrix corporate "Project Delivery" training program. This training encompasses all of the general aspects of project management as well as Parametrix and contract- or client-specific requirements and procedures.

Work Order Managers and Parametrix employees assigned to the contract receive QA program training on the contract-specific QMP and QAPPs. This training includes regular training updates on QA program revisions, QA tips, procedures, and protocols. On-the-job QA training also occurs during staff and management interaction on QA reviews, project assessments, and corrective actions.

Identified QA staff (Work Order QA Managers, and others) receives additional outside training in EPA procedures through participation in EPA courses and conferences, and participation in other regional and national conferences through professional organization affiliations.

QP 1.1 specifies the process, responsibilities, procedures, and documentation required for training. All of the items discussed below are covered in more detail in QP 1.1.

4.2 TRAINING NEEDS ASSESSMENT AND IMPLEMENTATION

It is the responsibility of the Project/Deputy Project Manager, Work Order Managers, and the QA Officer to:

- Ensure that work, including field operations, is performed by properly trained, qualified individuals with appropriate and necessary health and safety training.
- Select appropriate personnel by reviewing resumes and qualifications.
- Determine if additional training or retraining (e.g., based on changing requirements or corrective actions) is required.
- Specify and arrange for additional training or retraining, as required.

- Ensure proper documentation of all training is maintained in the corporate office of Parametrix and designated work order files.

Staff will maintain their qualifications through regular and additional training, as necessary, to meet changing quality requirements or system upgrades.

4.3 TRAINING DOCUMENTATION

As a matter of policy, Parametrix maintains documentation of all corporate-sponsored and other training that involves Parametrix staff. Documentation of training for subcontractor staff will not be maintained unless specifically required by a work order work plan or QAPP. Recordkeeping requirements and forms for the indoctrination and training process are provided in QP 1.1.

5. PROCUREMENT OF ITEMS AND SERVICES

Parametrix may procure items (e.g., measurement and test equipment) and technical services (e.g., laboratories, drillers, and surveyors) that directly affect the quality of results and work products. Procurement of these items and services is controlled to ensure proper quality. All procurements are processed to ensure that Parametrix policies and procedures and the Federal Acquisition Regulations are followed.

5.1 PROCUREMENT OF ITEMS

QP 2.1 provides the procedures, requirements, and responsibilities for the procurement of measurement and test equipment (M&TE). Purchase requisitions for M&TE include technical and quality requirements. To ensure that the requirements are appropriate for the work order, the Work Order Manager and Work Order QA Manager (or their designees) review and approve M&TE requirements. Certain M&TE may require acceptance testing, if specified in the technical and QA requirements. Upon receipt of M&TE, receipt inspection is performed to ensure that:

- No damage was sustained during shipment.
- The item received is the item ordered.
- Required documentation, such as certificates of calibration, is received and acceptable.
- Inspection and/or testing, if needed, is conducted to ensure conformance with specifications and requirements.

Nonconforming items identified during receipt inspection or acceptance testing are controlled according to QP 2.3.

5.2 PROCUREMENT OF SERVICES

QP 2.2 provides the procedures, requirements, and responsibilities for the procurement of technical services (i.e., subcontractors). To procure technical services, solicitation documents are prepared that specify what is required of the respondents and includes technical and quality requirements for the work, as directed. Solicitation documents are reviewed and approved by the Work Order Manager and Work Order QA Manager or other approved technical and QA reviewers, respectively. Major subcontractor solicitations, which may be used for more than one work order, are additionally reviewed and approved by the Project/Deputy Project Manager for consent.

In the subcontractor's response to the solicitation, objective evidence that documents their ability to adhere to the technical and quality requirements of the work is required. If appropriate, their adherence to work-order-specific QAPPs is required or, alternatively, the subcontractor may be required to submit evidence of an acceptable, internal QA program that equally achieves the goals of the QAPP.

Technical staff evaluate subcontractor proposals to ensure that they meet the required technical and quality requirements. Once accepted, the technical staff makes a recommendation to the Work Order Manager or the Project/Deputy Project Manager for procurement. Recommendations are ultimately reviewed and approved by the Work Order Manager.

Each resulting subcontract for professional services is patterned after the Parametrix/client contract. As appropriate, the subcontract document includes or cites:

- Terms and conditions of the prime contract.
- Applicable Federal Acquisition Regulations clauses.
- Applicable federal, state, and local standards.
- Required licenses, permits, and restrictions.
- Technical requirements.
- Work-order-specific requirements.
- QA requirements.
- Health and safety requirements.
- Documentation requirements.
- Right-of-access for audit.

Subcontracted activities are evaluated to ensure that the work conducted produces results of acceptable quality. Techniques for evaluating subcontractor service performance include, as appropriate:

- Document and deliverable review.
- Certificates of conformance for items provided by subcontractors.
- Audits and surveillances.
- Inspections or tests.

6. DOCUMENTS AND RECORDS

6.1 DOCUMENT CONTROL

A document is defined as information in any medium that describes, defines, specifies, reports, or certifies activities, requirements, procedures, or results pertaining to work conducted on the work order. Document control is the process of ensuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. The document control system is defined in QP 3.1 and provides for:

- Identification of documents to be controlled.
- Assignment of responsibility for preparation, review, approval, and issuance.
- Technical review of documents for adequacy, accuracy, and completeness before they are approved and issued for distribution.
- Updates of documents in a controlled and timely manner.

Environmental characterization and monitoring activities result in many documents that require review, approval, and distribution. Procedures, work order work plans, QAPPs, and logbooks are some of the documents to be controlled. A description of the technical and QA review process and requirements follow.

6.1.1 Technical Review

Technical review (which, as defined herein, incorporates an editorial review) is the process of checking the document for technical accuracy, accomplishment of work order objectives, and clarity of presentation. All documents containing technical information require an independent technical review. QP 3.2 provides the responsibilities, procedures, and documentation requirements for technical reviews.

6.1.2 Quality Assurance Review

QA review is a higher level review of a previously reviewed Parametrix document by the QA Officer or his designee to ensure that the document has, in fact, received an appropriate technical review and is in conformance with all quality requirements. Documents requiring QA review are specified in QP 3.3. QP 3.3 also outlines the responsibilities, procedures, and documentation requirements for the QA Officer's, or his designee's, review.

6.2 RECORDS CONTROL

The responsibilities, requirements, and procedures for identifying, validating, storing, retrieving, and disposing of records and documents are provided in QP 3.4. "Records" are defined as completed documents and other materials that provide objective evidence of the expected and achieved quality of items completed or activities performed. Records include, but are not limited to:

- Technical proposals, work order work plans (as necessary), and other work order planning documents.
- QAPP.
- Training records.

- Work order reports (including letter reports).
- Field notebooks.
- Chain-of-custody records.
- Audit reports.
- Field change notices.
- Laboratory data (including data validation).
- Completed technical/QA review forms.

The Work Order Manager defines work order documents that are expected to be records. Records are maintained in the Parametrix project office in a secure manner that prevents deterioration. A record indexing system, which allows for easy retrieval and provides sufficient information to permit the correlation of records with the items or activities to which they apply, is used. Inactive records are stored for a specified period of time (per contract), after which they are properly disposed of or transferred to the Client. Disposition of records is controlled and documented. Records are destroyed only after proper notification to the Client and following the approval of the Work Order Manager.

6.2.1 Custody Requirements for Project Documents

Parametrix or its subcontractors may be required to receive and/or maintain some documents (e.g., data packages) under chain-of-custody procedures. The Work Order Manager will, as defined in the work order work plan or QAPP, identify documents that require such handling.

6.2.2 Treatment of Confidential Business Information

A client, or pursuant to EPA FAR 1552.235-76 EPA's Contracting Officer (CO), may disclose Confidential Business Information (CBI) to Parametrix necessary to carry out the work required under the contract. Parametrix agrees to use the CBI only under the following conditions:

- For the purposes of carrying out the work required by the contract.
- To return to the Client or destroy all copies of the information and any abstracts or excerpts therefrom, upon request, whenever the information is no longer required by Parametrix for the performance of the work required by the contract, or upon completion of the contract.
- Obtain a written agreement to honor the above limitations from each employee who will have access to the information before the employee is allowed access.
- Not to disclose the information to anyone other than employees with signed agreements as noted above.
- To not use any CBI supplied by the Client or obtained during performance hereunder to compete with any business to which the CBI relates.

Parametrix will also obtain the written consent of the Client prior to entering into any subcontract that will involve the disclosure of CBI by Parametrix to the subcontractor. Parametrix will include all of the above conditions in all subcontracts awarded pursuant to this contract that require the furnishing of CBI to the subcontractor.

7. COMPUTER HARDWARE AND SOFTWARE

Control of computer hardware and software used for environmental data operations and engineering is necessary to ensure proper operation and compatibility, as well as the accuracy and compatibility of the resulting products.

7.1 COMMERCIALLY AVAILABLE HARDWARE AND SOFTWARE

If required in a work order work plan or QAPP, commercially available computer hardware and software used for designing environmental systems, performing computations, or database operations on environmental data is controlled to ensure the validity of the data generated.

QP 4.1 defines responsibilities, procedures, and documentation requirements for control of commercially available computer hardware and software. This control includes:

- Documentation of the system configuration initially, and after each modification.
- System testing before initial use and after any modification to ensure that no computational errors are generated.
- Evaluation of any proposed changes to the system, before they are implemented, to determine the impact of the change.

If commercial-grade software is used, it need not be tested; however, validation of representative calculations should be performed using alternate (e.g., manual) means.

7.2 SOFTWARE DEVELOPMENT

QP 4.2 addresses the responsibilities, procedures, and documentation requirements for control of software developed by Parametrix for use on computer hardware that is used for environmental data operations and engineering. The key elements of software quality assurance include:

- Selecting an appropriate national standard in consultation with the Client and/or regulatory agency with primary oversight responsibility.
- Following configuration management guidelines to prevent unauthorized changes or access to software programs.
- Verifying entries on data entry screens for relevant technical software to prevent data entry errors.
- Performing independent testing and review to verify that the specified requirements are met.
- Controlling changes to ensure that all proposed modifications are reviewed and approved.
- Evaluating documentation such as user and system support manuals for conformance with requirements and/or standards before release.

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8. IMPLEMENTATION OF WORK ORDER PROCESSES

To ensure the quality of the work order processes, all work must be performed by qualified employees following controlled planning documents and procedures and using the correct items and calibrated instruments. The level of supervisory oversight must be commensurate with the complexity, difficulty, and importance of the activities. The implementation of work order processes must be in accordance with the QMP, approved work order work plan (if required), and QAPP.

8.1 STAFF QUALIFICATIONS

The Work Order Managers determine the necessary qualifications for the project staff, evaluate and select staff, and specify required reading and any special training. QP 1.1 addresses personnel qualification and training.

8.2 PLANS AND PROCEDURES

Approved planning documents, discussed in Section 3.3, provide the technical and quality requirements for work order work. These plans are written, reviewed, and approved to ensure that work is conducted properly if the plans are followed. It may be necessary to revise these documents to reflect work order changes or to respond to EPA comments. Revisions are allowable, but they must be properly controlled. Revisions changing the technical content require the same reviews and approvals as the original document to verify that the recommended changes were made as prescribed.

Revisions to Parametrix quality documents may occur at any time. Parametrix will review this QMP in its entirety and make appropriate revisions at least annually. Likewise, for work order work that exceeds one year's duration, the work order QAPP will also be reviewed at least annually.

Procedures are written to provide instruction and standardization for routine activities. Each procedure is written to provide detail commensurate with the complexity of the task. Based on the type of work being performed, the sources for approved procedures include but are not limited to:

- Contract QMP.
- QAPPs.
- Technical SOPs.
- Published or industry-standard methods and procedures.
- Work-order-specific procedures.
- Client or regulatory agency furnished procedures.

QP 5.1 identifies the review and approval requirements for control of these plans and procedures and their revisions. Change control enables the ability to make changes such as field modifications that result from unforeseen conditions. QP 5.2 discusses responsibilities, procedures, and documentation requirements for change control. This procedure is not intended for general, planned work order modifications. Control of changes is required to ensure that the ramifications of the change are considered by staff at the appropriate level, and to ensure that a permanent record of the change is maintained to document the nature of and reason for the change. Minor changes are documented in field logbooks or work order

notebooks. Major changes require more formal documentation and approval. The definitions of major and minor changes are included in QP 5.2.

Project and work-order-specific plans, as well as any procedures specified in the plans, are required to be at the work order location and available to the work order staff. The Work Order Manager is responsible for ensuring that the work order staff have the current revisions of the plans and procedures, and ensuring that the documents are followed. The work order staff is responsible for being familiar with the plans and procedures, and performing work order activities in accordance with them.

8.3 WORK ORDER START-UP

Preparation for work order activities involves communicating to the project staff the:

- Goals of the work order.
- Technical and quality requirements.
- Individual responsibilities.
- Plans and procedures to be followed.
- Schedule.
- Potential problems.
- Equipment and supplies requirements.

This may be accomplished by a work order kickoff meeting or other staff meeting to ensure that the participants are familiar with their responsibilities and are able to raise and resolve any concerns they may have.

8.4 FIELD PLANNING MEETINGS

One or more field planning meetings are required for every work order involving field work. The Work Order QA Manager is responsible for identifying any special quality requirements and should attend the meeting if practical and necessary. If not, the Work Order QA Managers will offer input and review the agenda. The steps necessary to complete the fieldwork, as well as the requirements for each activity, are reviewed and discussed. This discussion also provides a forum for the project staff to identify and resolve any potential problems. Any problems identified during the field planning meeting, together with the agenda and attendance list, are maintained in the work order files.

8.5 CONTROL OF ITEMS AFFECTING QUALITY

8.5.1 Inspection and Testing

Certain environmental operations may require inspection or testing of an item, assembly, or process to determine if the item conforms to expectations before work order activities begin or continue. Examples of operations for which inspection or testing may be applicable are:

- Well installations.
- Waste treatment systems.

- Computer programs.
- Computer systems.

Inspection refers to the examination or measurement of an item to verify whether the item conforms to the specified requirement. Technically qualified personnel, other than those who performed or directly supervised any work on the item, perform these inspections. The requirement for inspections, hold points (if necessary), and the tentative schedule are specified in the work order planning documents. QP 5.3 specifies the procedures, responsibilities, and documentation requirements for inspections.

Testing refers to the verification of an item's capability or that a technique conforms to specified requirements. Item testing is done by subjecting the item to a set of physical, chemical, environmental, or operating conditions. Planning documents will identify any tests required and acceptance criteria for testing. QP 5.4 specifies procedures, responsibilities, and documentation requirements for testing.

8.5.2 Samples and Sample Custody

Due to the possible evidentiary nature of samples collected during the environmental investigations, possession must be traceable from the time samples are collected until their derived data are reported and/or introduced as evidence in legal proceedings. Identification of samples is accomplished through the use of unique identification numbers according to a specific format usually defined in the QAPP or work order work plan. For contractor-selected laboratories, Parametrix will limit the use of site names and sample locations to avoid any real or perceived conflict of interest between the site and the selected laboratory.

8.5.3 Measurement and Test Equipment

Procurement of M&TE is controlled according to QP 2.1. Calibration, use, and disposition are controlled according to QA 2.1 and manufacturer's specifications, which specify the calibration requirements, field checks, acceptance criteria, required documentation, and procedures for use for each piece of M&TE. The Work Order Manager, Work Order QA Manager, or CHSO may approve specific exemptions.

8.5.4 Nonconforming Items

Only items that conform to established specifications are used. Purchased items affecting the quality of work are inspected upon receipt. Other items may be identified as nonconforming during routine observation, inspection, or testing. Nonconforming items or samples will be identified and segregated or eliminated to prevent inadvertent installation and/or use. The early identification of nonconformance is critical to quality improvement. The system used to identify, segregate, and document nonconforming items and samples is specified in QP 2.3.

8.6 SUPERVISION AND OVERSIGHT

The Work Order Managers and/or the Field Team Leader supervise work order work. The Work Order QA Managers perform oversight and other technical tasks, as required. The frequency and detail of oversight activities will be commensurate with the complexity and importance of the activities and the intended use of the data.

8.6.1 Supervision of Work Order

The Work Order Manager is responsible for ensuring adherence to the work order planning documents and procedures and for the technical adequacy of the work order work. The Work Order Manager supervises the project staff at a level commensurate with the difficulty and complexity of the work and the specific experience of the staff.

8.6.2 Oversight of Work Order

Oversight of the work order processes is accomplished through the use of various types of assessments. These may include inspection, self-assessment, technical (peer) review, data assessment, surveillance, and audits. The assessments are scheduled, planned, and conducted as described in Section 9.0.

8.7 CONTROL OF SPECIAL PROCESSES

When the quality of the process is completely dependent on the employee's skill and the quality is not measurable, or when special codes, standards, specifications, criteria, or special requirements apply, the process shall be identified as a special process and controlled in the manner specified in the work order work plan or QAPP. QP 5.5 lists the responsibilities, procedures, and documentation requirements for control of special processes.

9. ASSESSMENTS AND RESPONSES

Assessments are a learning process intended to increase the user's understanding of the program or system being assessed, and to provide a basis for improving such programs or systems. The purpose of assessments is to improve the quality of work by comparing the system or element to the specified requirements. Assessments are conducted at least annually for the corporate and contract levels.

Response refers to the actions taken by the assessed organization as a result of the assessment. Typically, responses involve corrective actions to address deficiencies identified in the assessment. The following sections identify and describe the two major assessment types, management and technical; not all are applicable to each work order. The applicable assessment types will be specified in the work order work plan or QAPP. The Project Manager, Deputy Project Manager, Work Order Manager, or Work Order QA Manager may specify additional assessments, as necessary.

9.1 MANAGEMENT ASSESSMENTS

Management assessments evaluate the effectiveness of the QA system and its implementation. These assessments include self-assessments and independent assessments as described below. QP 6.1 covers this topic in greater detail.

9.1.1 Management Self-Assessment

A management self-assessment is the qualitative assessment of a particular program, project, or organization by those immediately responsible for overseeing and/or performing the work. This assessment establishes whether the prevailing quality management structure, policy, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained.

9.1.1.1 Management Systems Reviews

Management systems reviews are self-assessments conducted at the contract level by the QA Officer to establish whether the quality management structure, policies, and procedures are adequate to ensure quality data.

The primary focus of the management systems review is improving performance through:

- Fostering individual ownership of the quality program by increasing employee involvement in quality.
- Encouraging employees to routinely identify opportunities for quality improvement.
- Meeting with the Project Manager, Deputy Project Manager, Work Order Managers, Work Order QA Managers, and technical staff to solicit specific suggestions to improve quality, such as more practical implementation methods, procedural modifications, etc.
- Training the Project Manager, Deputy Project Manager, Work Order Managers, Work Order QA Managers, and technical staff on quality issues and requirements.
- Communicating lessons learned from other management systems reviews.
- Checking on implementation and effectiveness of the quality program for the contract.

The results of the management systems review are reported in a brief memorandum written by the QA Officer and communicated to the COO and Project/Deputy Project Manager.

9.1.2 Independent Management Assessments

An independent management assessment is the qualitative assessment of a program and/or organization by someone other than the group performing the work to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained. The purpose of the management independent assessment is to determine and take necessary response actions regarding:

- Effectiveness of the system of management controls that are established to achieve and ensure quality.
- Adequacy of resources and personnel provided to achieve and ensure quality in all activities.

Independent management assessments are conducted at the corporate level and the contract level. At the contract and work order levels, these assessments are performed by appropriate Parametrix staff selected by the QA Officer who are independent of the work order being assessed. The results of the management independent assessments are reported in a brief memorandum written by the QA Officer and communicated to the COO, Project Manager, and Deputy Project Manager.

9.2 TECHNICAL ASSESSMENTS

Technical assessments assess the qualitative and/or quantitative aspects of a work order assignment to measure the performance or effectiveness of the technical system with respect to documented requirements. Both self-assessments and independent technical assessments are conducted.

9.2.1 Technical Self-Assessments

Technical self-assessments are conducted as part of a work order by the technical or management staff associated with the work order. Technical self-assessment techniques used include:

- Calculation checking.
- Data quality assessments (DQAs).
- Data validations.
- Data report QA sections.
- Work order self-assessments.

9.2.1.1 Calculation Checking

Mathematical calculations performed on environmental measurements or design calculations must be independently checked periodically. The person performing the check must be technically capable of performing the calculations independently.

9.2.1.2 Data Quality Assessments

The quality of data used to characterize environmental processes and conditions must meet the intended use of the data. Each QAPP will include or reference data reduction, validation, and reporting procedures to ensure that QAPP data quality requirements are met. Data validation is performed to assess the data; data report QA sections assess the reported results and the qualities achieved and discuss the adherence to the governing documents. Both are addressed in detail in the following sections.

Data Validation

Data validation is the process of screening data and accepting, rejecting, or qualifying the data on the basis of sound, EPA-recognized criteria. Data validation must occur soon after data collection and be objective in its approach. It is particularly important that newly generated sampling and analysis data are technically reviewed to ensure that they are valid measurement data. The QAPP should identify the validation criteria to be used and the staff members who will validate the data. Although not formally validated, field sampling data are evaluated using the following criteria:

- Adherence to an approved sample collection procedure.
- Cleanliness of sampling equipment and containers.
- Collection of required QC samples.

Analytical laboratory data generated by subcontractor laboratories are usually evaluated by trained staff under the direction of the Work Order QA Managers or the Analytical Services Coordinator, who ensure that the proper chain of custody procedures were followed, the specified analytical methods were used, and that all holding times for sample preparation/extraction (if required) and analysis were met. Additional criteria are specified in the QAPP and may include (but are not limited to):

- Blank samples.
- Replicate samples.
- Calibration check samples.
- Surrogate compounds.
- Spiked samples.
- Audit samples.

Parametrix staff will only be responsible for validation of data generated through subcontractor laboratories.

Data Report QA Sections

Reports that present data resulting from Parametrix-generated field or laboratory measurements require a QA section addressing the quality of the data and its limitations. The QA section should be commensurate in size and detail with the measurements reported. A letter report may have a paragraph QA section; a Remedial Investigation Report may have a 10- to 20-page QA section.

Each QA section, no matter how brief, should address:

- Adherence to the document(s) governing the measurement work (e.g., work order work plans or QAPP). Deviations should be noted and explained. The potential

impact of any significant deviation from the plans should be assessed and documented.

- Precision, accuracy, and completeness of the data reported in quantitative terms. The precision, accuracy, and completeness actually achieved should be compared with the respective objectives set in the planning document(s) governing the measurement work.

Additional information that should be provided includes, as appropriate:

- Representativeness and comparability of the data in qualitative terms as compared with the objectives set for these parameters.
- Changes/revisions to the document(s) governing the measurement work.
- Summary of QC activities, including development of SOPs and QC procedures.
- Summary of QA activities:
 - Results of performance and/or system audits.
 - Description of quality problems found.
- Description of corrective actions taken.
- Specific information required by the Client or regulatory agency with primary oversight.

9.2.1.3 Work Order Self-Assessments

Work order self-assessments are evaluations of work order activities conducted by project personnel knowledgeable in the project requirements to determine if the technical requirements are being met. They are intended to provide rapid feedback to the project staff to facilitate timely corrective action. The Project/Deputy Project Manager selects work or activities for project self-assessments, as well as the personnel to conduct them, and coordinates with the QA Officer for scheduling. Project self-assessments are conducted using a checklist. A brief report, which may simply be the completed checklist listing both positive observations and deficiencies, is issued by the Work Order QA Manager and is then communicated to the Project Manager, Deputy Project Manager, QA Officer, and Work Order Manager.

The responsibilities and procedures for planning, preparing, conducting, reporting, and follow-up for project self-assessments are discussed in QP 7.1.

9.2.2 Technical Independent Assessments

A technical independent assessment is an evaluation process performed by Parametrix technical staff independent of the work order being assessed to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications, requirements, and objectives. The purpose of all assessments is to improve the quality of work through identification of potential problems and deficiencies. Assessments may include qualitative or quantitative evaluations. Technical independent assessments include:

- Technical document review.
- Performance audits.
- Field and laboratory audits.

- Field and laboratory surveillance.
- Inspections.
- External audits.

For technical independent assessments conducted by Parametrix, the Work Order QA Manager will issue a brief report summarizing the assessment findings and communicate this report to the Parametrix Project Manager, Deputy Project Manager, QA Officer, and Work Order Manager.

9.2.2.1 Technical Document Review

Technical document review refers to a recorded critical review of work by one or more qualified reviewers independent of the document being reviewed. The review is performed to ensure applicability, technical accuracy, accomplishment of work order objectives, and conformance to established requirements. Review procedures, responsibilities, and documentation requirements are specified in QP 3.2.

9.2.2.2 Performance Audits

Performance audits are quantitative checks on different segments of work order activity; they are most appropriate to sampling, field measurements, and laboratory analysis activities. Performance audit techniques include checks on sampling equipment volume measurements and the blind analysis of laboratory reference samples (see ASP, Appendix B). The results are compared to the known values to evaluate the performance.

9.2.2.3 Field and Laboratory Audits

Authorized technical staff independent of the activities audited conduct field and laboratory audits. Auditors for field activities and laboratory operations require technical expertise that is specific to the activity audited and must be authorized by the QA Officer. Their technical competence is necessary to determine if the technical work order observed is following the documented procedures and requirements. The responsibilities and procedures for planning, conducting, and closing-out audits are specified in QP 6.2.

9.2.2.4 Field and Laboratory Surveillance

Field and laboratory surveillance is an assessment of processes or activities conducted by an authorized auditor to verify conformance to specified requirements. Surveillance is similar to an audit, but is intended to be more immediate in providing feedback to the surveyed party. A written plan is not required, and the report is less formal than an audit report. The responsibilities and procedures for planning, conducting, reporting, and closing-out surveillances are specified in QP 6.3.

9.2.2.5 Inspections

An inspection is an examination or measurement of an item to determine if it conforms to the specified requirement. Technically qualified personnel, other than those who performed or directly supervised work on the item, perform inspections (Section 8.6.1 addresses the use of inspections). QP 5.3 specifies the procedures, responsibilities, and documentation requirements for inspections.

9.2.2.6 External Audits

External audits are audits of Parametrix work performed by, or commissioned by, the Client or regulatory agency with primary oversight responsibilities. It is Parametrix's policy to cooperate fully with external auditors. Parametrix considers it a benefit to be audited, in that such audits may make management aware of deficiencies that might otherwise be overlooked.

Personnel involved with the work should be available during the audit. All files and other related material should be well organized so that required documentation can be located during the audit. As appropriate, the Work Order QA Managers and/or QA Officer will assist with audit preparation and will participate during the audit.

9.3 FREQUENCY OF INDEPENDENT ASSESSMENTS

The frequency and types of assessments are based on the nature and duration of the work order work. Table 9-1 presents the minimum frequency for each type of independent assessment. The Work Order Managers may request that a work order be audited, but may not prevent the QA Officer from selecting a work order for audit.

Table 9-1. Assessment Frequency

Assessment Type	Minimum Frequency
Self Assessments	
Management Systems Review	One per year.
Calculation Checking	All calculations.
Data Validation	As prescribed in the QAPP.
Data Report QA Section	Every measurement report.
Project Self-Assessment	As determined by Project/Deputy Project Manager.
Independent Assessments	
Technical Review Committee	As determined by Project/Deputy Project Manager.
Technical Review	Every document containing technical information.
Management Assessment	One per year.
Work Order Audit	One per year.
Performance Audit	As required by Client or oversight regulatory agency.
Field Audit:	
• Sample Collection/Field Measurements	One per five weeks of field work order.
• Field Oversight with Split Sampling	As determined by QA Officer.
• Field Oversight of Construction	As determined by QA Officer.
Laboratory Audit or Surveillance:	
• Subcontractor Lab	One per year.

9.4 RESPONSE TO ASSESSMENTS

9.4.1 Purpose of Assessments

Assessments are a learning process intended to increase the user's understanding of the program or system being assessed and to provide a basis for improving such programs or systems. Assessments identify noteworthy practices and accomplishments and areas where improvement is required. To bring about improvement, management and staff must respond to assessment findings in a timely manner. When conditions needing corrective action are identified, the responsible person will identify the corrective action and implement it promptly.

9.4.2 Responses to Different Types of Assessments

Depending on the type of assessment, different types of responses are required, ranging from an immediate correction to a detailed investigation into a programmatic cause, followed by extensive corrective action plans and implementation schedules. The following sections describe responses appropriate or required for various types of assessments.

9.4.2.1 Management Systems Reviews

Part of the management systems review is a meeting among the work order staff and the QA Officer. This meeting emphasizes the interactive exchange of concerns and suggestions to improve the quality program. Suggestions received by the QA Officer are considered and, if viable and beneficial, are implemented by the Work Order QA Managers. Suggestions for revisions to the QMP, including quality procedures will be considered immediately, but usually retained until a planned revision of the QMP. Suggestions relevant to other operating groups are forwarded to the managers of those groups. The QA Officer makes suggestions, which are discussed, then management takes appropriate action. The QA Officer documents the responses in a brief memo to the work order staff.

9.4.2.2 Management Assessment of the QA Program

Management assessment findings and recommendations are reported to the COO and Project Manager/Deputy Project Manager. They review the report and discuss its recommendations with the QA Officer, who distributes the report to senior management. The COO and Project Manager/Deputy Project Manager, in consultation with the QA Officer, evaluate the recommendations in terms of benefit, resource requirements, ability to implement, impact on the firm, unintended consequences, and schedules for implementation. They determine the final response and assign responsibilities and implementation schedules as necessary.

9.4.2.3 Technical Self-Assessments

Discrepancies identified by calculation checking are discussed by the originator and the checker and are resolved to technical correctness, if possible. If resolution cannot be reached, the Work Order Manager or designee works to resolve the discrepancy.

DQA Screens Data for Acceptability. Data may be accepted, rejected, or qualified. The response to rejected or qualified data may include re-analysis or resampling as determined by the Work Order Manager, based on DQOs and laboratory SOW for the work.

Technical document review typically results in comments on the draft document that require resolution before the document can be issued. The author, the Work Order Manager, and the reviewer interact as necessary to resolve comments. If resolution cannot be reached, the Project/Deputy Project Manager is contacted to provide resolution. The technical reviewer

may require a follow-up review to verify that review comments have been adequately addressed. The issued document is the final response to the technical review. QP 3.2 specifies the procedural steps required for response to technical review comments.

9.4.2.4 Audits and Surveillance

Deficiencies identified in audits require specific responses. Many deficiencies can be corrected quickly. Rapid correction is preferred, whenever possible, because of the immediate benefit to the work order activities. Rapid corrective action is most applicable to isolated mistakes, equipment malfunctions, and deficiencies that are easily corrected. Satisfactory corrective actions performed during an audit that can be verified by the auditor before the audit report is issued are considered rapid. The deficiency and corrective action taken are discussed in the audit report. For deficiencies that cannot be corrected rapidly, the auditor identifies the need for corrective action through the use of a CAR form. This form is sent to the Work Order QA Manager for:

- Determination if the deficiency is a significant condition adverse to quality.
- Assignment of responsibility for the response.
- Assignment of a required response date.

The person identified by the Work Order QA Manager must provide a satisfactory response by the required date. A satisfactory response may be evidence that the corrective action has been implemented and appropriate actions have been taken to prevent recurrence, or a plan of action with specific activities and dates for completion. The Work Order QA Manager is responsible for determining the acceptability of the response. If a satisfactory response is not received shortly after the required date, the CAR is reissued to the QA Officer for action. Further discussion of the corrective action system is located in Section 9.5 and QP 8.1, "Corrective Action."

9.5 CORRECTIVE ACTION SYSTEM

Perhaps the single most important part of any QA program is a well-defined policy for correcting quality problems. Parametrix maintains a closed-loop corrective action system under the direction of the QA Officer with full management support. While the entire QA program operates to prevent problems, it also serves to identify and correct those that may exist.

Corrective actions are required when an item, condition, or situation detrimental to quality is identified. This may include deviation from prescribed methods, items exceeding predetermined acceptability limits, or failure to meet performance requirements or data quality objectives. Anyone that finds a problem is responsible for reporting it. During routine activities, the majority of corrective actions can be implemented immediately by the work order staff and documented in work order notebooks. If the condition is not quickly corrected, the individual initiates a CAR form. The QA Officer can authorize the Work Order QA Managers to process CAR forms and evaluate and accept corrective actions. CAR forms are sent to the Work Order Managers, who assign responsibility for the corrective action and the required timing for the response. The Work Order QA Managers are responsible for tracking, reviewing, accepting, and verifying corrective actions. QP 8.1 describes the responsibilities and procedures associated with corrective actions.

The QA Officer maintains a CAR log that documents the date each CAR was initiated, identifies the originator, briefly cites the problem, and lists follow-up and completion dates.

9.5.1 Organizational Corrective Action

The individual or group who identifies the need for organizational corrective action informs the Work Order QA Managers or QA Officer. The QA Officer may meet with this group to discuss the situation and potential action. If appropriate, a task force is appointed by the QA Officer to study the situation and recommend the corrective action to be taken.

The recommendations of the task force are submitted to the QA Officer and COO in a confidential report for review and approval. If approved, the corrective action is implemented firm-wide.

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10. QUALITY IMPROVEMENT

The goal of any quality program is continuous improvement. The preceding sections have dealt with systems and management activities to ensure quality. Quality improvement is fundamentally the individual responsibility of every contract and work order staff member. Parametrix subcontractors will also be encouraged to implement similar quality improvement systems.

10.1 INDIVIDUAL RESPONSIBILITY

Each staff member, in some fashion, will perform work for a “customer” and is responsible for the quality of the work performed. The customer may be a regulatory agency or other public or private client, Parametrix as the prime contractor, a subcontractor, or simply another employee. Each person must determine the expectations of the individual customer and suggest to their supervisor ways of meeting those expectations. The person performing the task is usually the person most familiar with the task; their ideas are of great value and can often lead to significant improvements. It is the responsibility of each person to be proactive in addressing quality opportunities and issues by identifying to their supervisor any changes that may improve quality, any condition that could adversely affect quality, or any condition that could risk the safety of the staff.

10.2 NO-FAULT ATTITUDE

Parametrix fosters a no-fault attitude concerning problem identification and resolution. A no-fault attitude encourages everyone to participate actively in identifying potential problem areas for staff to address jointly. If desired, Parametrix employees may choose to identify deficiencies anonymously using the options discussed in the following section.

10.3 IDENTIFYING IMPROVEMENT OPPORTUNITIES

The improvement systems of Parametrix are described below.

10.3.1 Employee Level

Employees at all levels are encouraged to identify opportunities for improvement. Improvements may be:

- Easier-to-implement QPs and SOPs.
- More efficient work processes.
- Enhancements to work products.
- Cost-reduction measures.

Individuals should be “quality proactive” and actively look for improvement opportunities.

Improvement suggestions can be made to the employee’s immediate supervisor, Work Order QA Manager, or QA Officer. Additionally, the QA Officer is always accessible to employees by phone, fax, or e-mail.

10.3.2 Contract and Work Order Level

Assessments at the contract and work order level identify specific opportunities for improvement. These assessments include:

- Contract trend analyses conducted by QA staff to review quality performance on a contract level and identify improvement opportunities.
- Office audits and surveillances conducted by QA staff to identify improvement opportunities.
- Field and laboratory audits and surveillance conducted by technical auditors to identify improvement opportunities.
- Project self-assessments conducted by the work order technical staff to identify improvement opportunities.

10.3.3 Corporate Level

The following two assessment types are applicable at the corporate level; each one uses different corporate resources to identify opportunities for improvement:

- **Management Assessments:** Uses an independent quality consultant or internal committee to identify improvement opportunities.
- **Management System Reviews:** Uses the QA Officer and selected staff to identify improvement opportunities.

10.4 IMPLEMENTING IMPROVEMENTS

The continuous improvement plan of Parametrix includes four elements, as briefly described below:

- **Establish Baseline and Goals:** Determine existing conditions and performance levels (e.g., current processes, procedures, systems), and identify goals or criteria to improve performance.
- **Identify Measurements:** Define measurements that will be used to assess how well new performance goals are being met.
- **Perform Monitoring:** Take measurements and compare them to the baseline and goals over time to determine if the goals are being met and whether adjustments or corrections need to be made.
- **Make Adjustments:** Implement necessary changes to the processes, procedures, organization, etc., to ensure that the new performance goals are being met.

When appropriate, these elements may be used in an iterative process to continuously improve a process or system. In this case, the new performance goal, when reached, becomes the baseline subject to further improvement and new goals are set.

All appropriate levels of management consider suggestions for improvements. If the suggestions are accepted, responsibility for implementation is assigned by the appropriate management level and tracked to completion. Responses to assessments and the associated corrective actions bring about quality improvement. The corrective action system as described in Section 9.5 and QP 8.1 ensures the timely implementation of corrective actions. The QA Officer conducts follow-up activity as appropriate.

Part II - Draft Quality Management Plan Quality Procedures - Revision No. 1

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August 28, 2008

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APPROVALS

Part II Draft Quality Procedures

Prepared for

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Date

Parametrix, William Stubblefield, Project Manager

Date

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TABLE OF CONTENTS

1. PERSONNEL QUALIFICATIONS AND TRAINING.....	1-1
1.1 QUALIFICATION AND TRAINING	1-1
1.1.1 Title.....	1-1
1.1.2 Purpose	1-1
1.1.3 Scope.....	1-1
1.1.4 Related Procedures	1-1
1.1.5 Definitions	1-1
1.1.6 Responsibilities.....	1-2
1.1.7 Procedures.....	1-2
1.1.8 Records	1-3
1.1.9 References.....	1-3
1.1.10 Exhibits.....	1-3
2. PROCUREMENT.....	2-1
2.1 PROCURING MEASUREMENT AND TEST EQUIPMENT.....	2-1
2.1.1 Title.....	2-1
2.1.2 Purpose	2-1
2.1.3 Scope.....	2-1
2.1.4 Related Procedures	2-1
2.1.5 Definitions	2-1
2.1.6 Responsibilities.....	2-2
2.1.7 Procedures.....	2-2
2.1.8 Records	2-3
2.1.9 References.....	2-3
2.1.10 Exhibits.....	2-4
2.2 PROCURING TECHNICAL SERVICES.....	2-5
2.2.1 Title.....	2-5
2.2.2 Purpose	2-5
2.2.3 Scope.....	2-5
2.2.4 Related Procedures	2-5
2.2.5 Definitions	2-6
2.2.6 Responsibilities.....	2-6
2.2.7 Procedures.....	2-7
2.2.8 Records	2-8
2.2.9 References.....	2-8
2.2.10 Exhibits.....	2-8
2.3 CONTROL OF NONCONFORMING ITEMS	2-9
2.3.1 Title.....	2-9
2.3.2 Purpose	2-9
2.3.3 Scope.....	2-9
2.3.4 Related Procedures	2-9

2.3.5	Definitions	2-9
2.3.6	Responsibilities.....	2-10
2.3.7	Procedures.....	2-10
2.3.8	Records	2-11
2.3.9	References.....	2-11
2.3.10	Exhibits	2-11
3.	DOCUMENTS AND RECORDS	3-1
3.1	DOCUMENT CONTROL.....	3-1
3.1.1	Title.....	3-1
3.1.2	Purpose	3-1
3.1.3	Scope.....	3-1
3.1.4	Related Procedures	3-1
3.1.5	Definitions	3-1
3.1.6	Responsibilities.....	3-2
3.1.7	Procedures.....	3-2
3.1.8	Treatment of Confidential Business Information (CBI)	3-3
3.1.9	Records	3-4
3.1.10	References.....	3-4
3.1.11	Exhibits.....	3-4
3.2	TECHNICAL DOCUMENT REVIEW	3-5
3.2.1	Title.....	3-5
3.2.2	Purpose	3-5
3.2.3	Scope.....	3-5
3.2.4	Related Procedures	3-5
3.2.5	Definitions	3-5
3.2.6	Responsibilities.....	3-5
3.2.7	Procedures.....	3-6
3.2.8	Records	3-8
3.2.9	References.....	3-8
3.2.10	Exhibits.....	3-8
3.3	QUALITY ASSURANCE REVIEW	3-9
3.3.1	Title.....	3-9
3.3.2	Purpose	3-9
3.3.3	Scope.....	3-9
3.3.4	Related Procedures	3-9
3.3.5	Definitions	3-9
3.3.6	Responsibilities.....	3-10
3.3.7	Procedures.....	3-10
3.3.8	Records	3-12
3.3.9	References.....	3-12
3.3.10	Exhibits.....	3-12
3.4	RECORDS CONTROL	3-13
3.4.1	Title.....	3-13
3.4.2	Purpose	3-13

TABLE OF CONTENTS (CONTINUED)

3.4.3	Scope.....	3-13
3.4.4	Related Procedures	3-13
3.4.5	Definitions	3-13
3.4.6	Responsibilities	3-14
3.4.7	Procedures.....	3-14
3.4.8	Records	3-15
3.4.9	References.....	3-16
3.4.10	Exhibits	3-16
4.	COMPUTER HARDWARE AND SOFTWARE	4-1
4.1	CONTROL OF COMPUTER HARDWARE AND SOFTWARE.....	4-1
4.1.1	Title.....	4-1
4.1.2	Purpose	4-1
4.1.3	Scope.....	4-1
4.1.4	Related Procedures	4-1
4.1.5	Definitions	4-1
4.1.6	Responsibilities	4-2
4.1.7	Procedures.....	4-2
4.1.8	Records	4-3
4.1.9	References.....	4-3
4.1.10	Exhibits	4-3
4.2	CONTROL OF DEVELOPED SOFTWARE	4-5
4.2.1	Title.....	4-5
4.2.2	Purpose	4-5
4.2.3	Scope.....	4-5
4.2.4	Relate Procedures	4-5
4.2.5	Definitions	4-5
4.2.6	Responsibilities	4-6
4.2.7	Procedures.....	4-6
4.2.8	Records	4-7
4.2.9	References.....	4-7
4.2.10	Exhibits	4-7
5.	CONTROL OF WORK PROCESSES	5-1
5.1	PREPARATION OF QUALITY PROCEDURES	5-1
5.1.1	Title.....	5-1
5.1.2	Purpose	5-1
5.1.3	Scope.....	5-1
5.1.4	Related Procedures	5-1
5.1.5	Definitions	5-1
5.1.6	Responsibilities	5-1
5.1.7	Procedures.....	5-2
5.1.8	Records	5-2

5.1.9	References.....	5-2
5.1.10	Exhibits.....	5-2
5.2	CHANGE CONTROL.....	5-5
5.2.1	Title.....	5-5
5.2.2	Purpose	5-5
5.2.3	Scope.....	5-5
5.2.4	Related Procedures	5-5
5.2.5	Definitions	5-5
5.2.6	Responsibilities.....	5-6
5.2.7	Procedures.....	5-6
5.2.8	Records	5-7
5.2.9	References.....	5-7
5.2.10	Exhibits.....	5-7
5.3	INSPECTION OF ITEMS.....	5-11
5.3.1	Title.....	5-11
5.3.2	Purpose	5-11
5.3.3	Scope.....	5-11
5.3.4	Related Procedures	5-11
5.3.5	Definitions	5-11
5.3.6	Responsibilities.....	5-11
5.3.7	Procedures.....	5-12
5.3.8	Records	5-13
5.3.9	References.....	5-13
5.3.10	Exhibits.....	5-13
5.4	TESTING.....	5-15
5.4.1	Title.....	5-15
5.4.2	Purpose	5-15
5.4.3	Scope.....	5-15
5.4.4	Related Procedures	5-15
5.4.5	Definitions	5-15
5.4.6	Responsibilities.....	5-15
5.4.7	Procedures.....	5-16
5.4.8	Records	5-16
5.4.9	References.....	5-16
5.4.10	Exhibits.....	5-16
5.5	CONTROL OF SPECIAL PROCESSES	5-19
5.5.1	Title.....	5-19
5.5.2	Purpose	5-19
5.5.3	Scope.....	5-19
5.5.4	Related Procedures	5-19
5.5.5	Definitions	5-19
5.5.6	Responsibilities.....	5-19
5.5.7	Procedures.....	5-20
5.5.8	Records	5-20

TABLE OF CONTENTS (CONTINUED)

5.5.9	References.....	5-20
5.5.10	Exhibits	5-20
6.	INDEPENDENT ASSESSMENTS	6-1
6.1	MANAGEMENT ASSESSMENT OF THE QA PROGRAM.....	6-1
6.1.1	Title.....	6-1
6.1.2	Purpose	6-1
6.1.3	Scope.....	6-1
6.1.4	Related Procedures	6-1
6.1.5	Definitions	6-1
6.1.6	Responsibilities.....	6-1
6.1.7	Procedures.....	6-1
6.1.8	Records	6-2
6.1.9	References.....	6-2
6.1.10	Exhibits	6-2
6.2	AUDITS.....	6-3
6.2.1	Title.....	6-3
6.2.2	Purpose	6-3
6.2.3	Scope.....	6-3
6.2.4	Related Procedures	6-3
6.2.5	Definitions	6-3
6.2.6	Responsibilities.....	6-4
6.2.7	Procedures.....	6-4
6.2.8	Records	6-5
6.2.9	References.....	6-6
6.2.10	Exhibits	6-6
6.3	QUALITY ASSURANCE SURVEILLANCES.....	6-9
6.3.1	Title.....	6-9
6.3.2	Purpose	6-9
6.3.3	Scope.....	6-9
6.3.4	Related Procedures	6-9
6.3.5	Definitions	6-9
6.3.6	Responsibilities.....	6-10
6.3.7	Procedures.....	6-10
6.3.8	Records	6-12
6.3.9	References.....	6-12
6.3.10	Exhibits	6-12
7.	PROJECT SELF-ASSESSMENTS.....	7-1
7.1	WORK ORDER SELF-ASSESSMENTS	7-1
7.1.1	Title.....	7-1
7.1.2	Purpose	7-1

7.1.3	Scope.....	7-1
7.1.4	Related Procedures	7-1
7.1.5	Definitions	7-1
7.1.6	Responsibilities.....	7-1
7.1.7	Procedures.....	7-2
7.1.8	Records	7-3
7.1.9	References.....	7-3
7.1.10	Exhibits.....	7-3
8.	RESPONSE TO ASSESSMENTS	8-1
8.1	CORRECTIVE ACTION	8-1
8.1.1	Title.....	8-1
8.1.2	Purpose	8-1
8.1.3	Scope.....	8-1
8.1.4	Related Procedures	8-1
8.1.5	Definitions	8-1
8.1.6	Responsibilities.....	8-2
8.1.7	Procedures.....	8-2
8.1.8	Records	8-4
8.1.9	References.....	8-4
8.1.10	Exhibits.....	8-4
9.	CONTINUOUS IMPROVEMENT	9-1
9.1	CONTINUOUS IMPROVEMENT	9-1
9.1.1	Title.....	9-1
9.1.2	Purpose	9-1
9.1.3	Scope.....	9-1
9.1.4	Related Procedures	9-1
9.1.5	Definitions	9-1
9.1.6	Responsibilities.....	9-1
9.1.7	Procedures.....	9-2
9.1.8	Records	9-3
9.1.9	References.....	9-3
9.1.10	Exhibits.....	9-3

ACRONYMS AND ABBREVIATIONS

CAR	Corrective Action Request
CBI	Confidential Business Information
CO	Contracting Officer
COO	Chief Operating Officer
DO	Dissolved Oxygen
EPA	Environmental Protection Agency
FARs	Federal Acquisition Regulations
HRIS	Human Resources Information Systems
HSPs	Health and Safety Plans
ITD	Information Technology Division
LEL	Lower explosive limit
M&TE	Measurement and test equipment
OVA	Organic vapor analyzers
OVM	Organic vapor monitors
PID	Photoionization detectors
QA	Quality Assurance
QA/QC	Quality Assurance and Quality Control
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QP	Quality Procedure
RFP	Request for Proposal
SCT	Salinity, conductivity, temperature
SOPs	Standard Operating Procedures
SOW	Statement of Work
WBS	Work Breakdown Structure

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1. PERSONNEL QUALIFICATIONS AND TRAINING

1.1 QUALIFICATION AND TRAINING

Prepared By:	_____	Date:	_____
	Jeanna Hanenburg		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

1.1.1 Title

Qualifications and Training.

1.1.2 Purpose

To describe the personnel qualifications and training program at Parametrix.

1.1.3 Scope

This procedure applies to contract and work-order-specific qualifications and training of Parametrix employees who are performing activities affecting quality.

1.1.4 Related Procedures

None.

1.1.5 Definitions

Qualification describes the technical background or experience required for work order work, as determined by the Project/Deputy Project Manager or a designated Work Order Manager.

Training and Orientation represents in-house classroom sessions, briefings, on-the-job instruction, required reading assignments, and other related avenues of study that provide orientation, motivation, instruction, skills, and direction related to fundamental topics of the project, including quality assurance (QA) requirements.

Certification is an authorization that allows an individual to perform specialized tasks or to officially practice a certain profession. Certifications are documented and maintained by professional societies and the states in which the certification was given. Certifications for employees are maintained in the Parametrix Human Resources Information Systems (HRIS) database.

1.1.6 Responsibilities

The following lists specific activities for which individuals are responsible in the qualifications and training program:

- **Project/Deputy Project Manager and/or Designated Work Order Manager**
 - Determining the required employee qualifications for each work order assignment.
 - Evaluating employee's qualifications.
 - Specifying training assignments.
 - Arranging training sessions, including qualified instructors, classroom space, and materials.
 - Ensuring that employees complete assignments.
 - Ensuring that proper documentation is completed and maintained.
- **Human Resources**
 - Collecting certification, education, and training data from employees and maintaining it within the Parametrix HRIS database.
 - Providing input as required to the Project and Work Order Managers, when requested, on the certification and educational level of employees.

1.1.7 Procedures

The following outlines the QA review procedure:

- **Determination of Qualifications:** The Work Order Manager will determine the education, experience, certification, and qualifications necessary for the work order.
- **Initial Evaluation of Qualifications:** The Work Order Manager will review the employee's education, experience, and certifications and compare them to the qualifications necessary for the work order. If the employee's qualifications are not appropriate, further training may be necessary.
- **Training:** The Project/Deputy Project Manager or Work Order Manager will arrange for qualified instructors, classroom space, and materials for the training sessions. Ongoing internal and external training for specific areas of study in leadership, management, teamwork, human relations, communication, and quality assurance are provided. The Project/Deputy Project Manager or Work Order Manager may request a list of employees from Human Resources that includes current education level, certification, training, and applicable technical skills training in determining training requirements for a project. Attendance at training sessions is recorded on an attendance roster (Exhibit 1.1) and then forwarded to Human Resources for input into the HRIS database for storage and maintenance.
- **Documentation:** The Work Order Manager will track the status of training assignments and document completed assignments in the work order files. Tracking will be completed by using the Parametrix HRIS database (Exhibit 1.2).

1.1.8 Records

The following records, or their equivalents, will be maintained in the HRIS:

- Initial evaluation of qualifications.
- Training attendance lists.
- Certificates of qualifications.

1.1.9 References

None.

1.1.10 Exhibits

The following exhibits are attached:

- Exhibit 1.1 – Training Attendance Roster.
- Exhibit 1.2 – HRIS Report of Certification, Training, and Education.

EXHIBIT 1.1
Parametrix
Training Attendance Roster

Program/Task: _____
Subject of Training: _____
Date/Time: _____
Location: _____
Instructor(s): _____

Attendees:

Print Name	Signature
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Submit Form to HR for input in HRIS Training file.

EXHIBIT 1.2

HRIS Report of Certification, Training, and Education (Sample)

Employee	Grade Code	SSN	Title	Skill Description	Office	Degree Code	Education Major Description	Training Code	Training Description	Training Date	Licenses
Sample Name	15	000-00-0000	Sr. Engineer	Project Manager	Sumner Office	BS	Civil Engineering	C-BD1	Presentation Skills – 1	18-Jul-00	PE
						MS	Environmental Engineering	C-BD2	Presentation Skills – 2	18-Jul-00	
								C-BD3	Client & Market Propositioning	9-Apr-01	
								C-FD1	Foundations - Company Basics	3-Nov-00	
								C-MS1	Doing a Breakdown Structure	24-Jun-02	
								C-MS2	Work Breakdown with MS Project	25-Jun-02	
								C-MS3	How To Link Your Job Schedule	28-Jun-02	
								C-PD1	"Roll-out" Presentation of P.D.	1-Sep-00	
								C-PD2	Project Life Cycle Training	7-Dec-00	
								C-PD3	Contract Development	26-Jan-01	
								C-PD6	Project Delivery QA/QC	19-Sep-01	
								C-PD7	Project Delivery-Change Management	22-Jan-02	
								PCT	Participatory Culture Training	1-Mar-02	
								SUP1	Supervisor Training Session 1	12-Sep-01	
								SUP2	Supervisor Training Session 2	10-Oct-01	
								SUP3	Supervisor Training Session 3	14-Nov-01	
								SUP4	Supervisor Training Session 4	12-Dec-01	
								SUP6	Supervisor Training Session 6	13-Feb-02	
								SUP7	Supervisor Training Session 7	13-Mar-02	
								SUP8	Supervisor Training Session 8	10-Apr-02	

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2. PROCUREMENT

2.1 PROCURING MEASUREMENT AND TEST EQUIPMENT

Prepared By:	_____	Date:	_____
	Janice Walden		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

2.1.1 Title

Procuring Measurement and Test Equipment.

2.1.2 Purpose

To describe the system at Parametrix for procuring measurement and test equipment (M&TE) in a manner that meets work-order-specific technical and quality requirements.

2.1.3 Scope

This procedure applies to the purchase or rental of commercial grade M&TE, including standards and reference materials for calibrations.

M&TE that is not considered commercial grade may require special procurement procedures; contact the QA Officer for these procedures.

2.1.4 Related Procedures

Other procedures related to control of nonconforming items include:

- Quality Procedure (QP) 2.3 – Control of Nonconforming Items.

2.1.5 Definitions

M&TE (measurement and test equipment) are tools, gauges, instruments, monitoring equipment, sampling devices, calibration, and reference materials, or systems used to calibrate, measure, test, or inspect in order to control or acquire measurement data. M&TE also includes standards and reference materials used to calibrate instruments.

Commercial Grade M&TE represents M&TE ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., catalog).

Receipt Inspection is the examination of a package to check for obvious damage and to ensure that the items received match, in quantity and description, those listed on the packing slip.

Acceptance is verification that the goods received match those ordered as shown on the purchase order, and are free from damage and defects and acceptable for use. Acceptance testing may be necessary to verify performance.

Acceptance Testing is a performance evaluation of certain M&TE to determine compliance with requirements or published specifications. Acceptance testing is not required for M&TE unless specified by the requisitioner.

2.1.6 Responsibilities

Responsibilities for procuring M&TE include the following:

- **Requisitioner**
 - Determining work-order-specific technical and quality requirements for M&TE.
 - Determining if acceptance testing should be performed.
 - Ensuring procurement is consistent with corporate procurement policy at Parametrix.
 - Determining the acceptability of purchased items.
 - Arranging for and documenting acceptance testing, if required.
 - Handling any nonconforming items in accordance with QP 2.3, if required.
- **Work Order Manager or His/Her Designee**
 - Reviewing/approving of Procurement Requests.
- **Procurement Staff**
 - Verifying that the Procurement Request has been approved before procuring items.
 - Procuring M&TE that meets the technical and quality requirements as specified.
 - Maintaining required documentation in the procurement file.

2.1.7 Procedures

The procedures listed below shall be followed when procuring M&TE:

- **Determine the M&TE Requirements:** The requisitioner will determine the work-order-specific M&TE requirements based upon requirements of the Work Order Work Plan. Requirements include, as applicable, measurement or parameter, range, accuracy, detection limit, calibration traceability, special operating conditions, etc. The requisitioner may also need to determine if acceptance testing is required prior to first use.

The Procurement Request shall include the following work-order-specific information:
 - Work order title and number.
 - Special requirements.
 - Acceptance testing requirement, if applicable.
 - Calibration requirements.
- **M&TE without Standard Requirements:** For M&TE for which standard requirements have not been established, the requisitioner will determine the requirements appropriate for that work order and list them in the Procurement Request.

- **Review/Approval:** Review and approval of the Procurement Request will be completed as listed below.
 - Work Order Manager, Work Order QA Manager, or Designees: The Work Order Manager, QA Manager, or designees will review the procurement requirements to verify that the requested M&TE is consistent with the work order requirements as specified in the Work Order Work Plan. If acceptable, the reviewer will sign the Procurement Request and forward it to the procurement staff.
- **Procure M&TE:** To procure M&TE, the procurement staff will complete the tasks listed below.
 - Verify approval on the Procurement Request.
 - Generate a purchase order that specifies the M&TE and requirements consistent with the specifications on the purchase requisition/M&TE Request Form (e.g., calibration requirements and documentation).
 - State on the purchase order that acceptance testing is required, if appropriate.
 - Maintain the Procurement Request in the procurement file.
- **Receipt and Acceptance/Rejection of M&TE:** The procurement procedures listed below define the steps for receipt of goods and acceptance/ rejection of goods.
 - Receipt Inspection: Designated staff will check for obvious damage and verify the quantity and item description against the packing slip. Receipt inspection is conducted and documented according to the procurement procedures.
 - Acceptance of M&TE: A determination will be made whether an item is acceptable for use. Acceptance testing is not required unless specified on the Procurement Request. The requisitioner or an appropriately qualified individual will determine the acceptability and document either the acceptance or rejection of the M&TE according to the procurement procedures.
 - Rejection: M&TE that is not accepted is rejected and is considered nonconforming. The requisitioner is responsible for ensuring that nonconforming M&TE is segregated to prevent inadvertent use. Nonconforming situations will be addressed by applying relevant sections of QP 2.3, "Control of Nonconforming Items."

2.1.8 Records

The procurement files will include the following records:

- Procurement Request forms.
- Copies of acceptance testing results, if applicable.
- Documentation of acceptance/rejection, if applicable.
- Nonconformance reports, if applicable.

2.1.9 References

None.

2.1.10 Exhibits

The following exhibit is attached:

- Exhibit 2.1 – Examples of Measurement and Test Equipment.

EXHIBIT 2.1

Examples of Measurement and Test Equipment

The following list only identifies the most commonly purchased M&TE and is not intended to be a definitive listing:

- Organic vapor analyzers (OVA)
- Organic vapor monitors (OVM)
- Photoionization detectors (PID)
- Salinity, conductivity, temperature (SCT) meters
- Lower explosive limit (LEL) meters
- Thermometers
- Calibration gases (methane in nitrogen, isobutylene, etc.)
- pH meters and standards (buffers)
- Dissolved oxygen (DO) meters
- Pressure transducers
- Air samplers
- Hach test kits
- Draeger pumps and tubes
- Radiation meters
- Flow controllers
- Pressure gauges
- Magnehelic® gauges
- Combustible gas indicators
- Gas meters

The following are usually not considered M&TE (check specific project requirements):

- Rulers
- Water level indicators
- Shipping scales

2.2 PROCURING TECHNICAL SERVICES

Prepared By:	_____	Date:	_____
	Bob Rosain		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

2.2.1 Title

Procuring Technical Services.

2.2.2 Purpose

To present the quality procedure for procuring technical services at Parametrix.

2.2.3 Scope

This procedure applies to the procurement of technical services using subcontract agreements. It applies to both competitive and sole-source procurements, and to team subcontracts as well as pool subcontracts for technical services.

This procedure does not apply to non-technical standardized services (e.g., clerical, office equipment maintenance, security services, and graphics services). Additionally, this procedure does not apply to Requests for Qualifications.

Technical review and QA review requirements apply to:

- Solicitations including, but not limited to, requests for bid and requests for proposals (RFPs).
- Sole-source subcontracts, including team subcontracts.

Technical evaluation and quality evaluation requirements apply to all technical responses to RFPs and the validation and confirmation of responsiveness of apparent low bids.

Changes to technical requirements of procurement documents (i.e., amendments) during the solicitation stage require the same level of review and approval as the original solicitation documents. Modifications to active subcontracts require technical and QA review. The review requirement is commensurate with the complexity of the amendment.

2.2.4 Related Procedures

Other procedures related to procuring technical services include:

- Parametrix procurement procedures.

2.2.5 Definitions

Solicitation is any request for a proposal or bid.

Technical Requirements are statements of work (SOWs), technical specifications, and technical evaluation criteria, descriptions of performance standards, requirements for deliverables and/or reporting and other technical components of solicitations.

Responses to Solicitations are the technical proposal and/or technical qualifications submitted in response to a solicitation.

Technical Services are defined as services, both professional and nonprofessional, which require special training, experience, or knowledge.

2.2.6 Responsibilities

Responsibilities for procuring technical services include:

- **Work Order Managers**
 - Preparing technical requirements.
 - Obtaining appropriate technical and QA reviews of the technical requirements.
 - Providing evidence of technical and QA reviews of the technical requirements.
 - Submitting technical requirements to procurement staff.
 - Participating on technical evaluation panels responsible for evaluating technical responses to solicitations.
- **Technical Reviewers**
 - Reviewing technical requirements, verification methods, and technical evaluation criteria.
 - As necessary, evaluating technical responses to solicitations for capability to meet technical and quality requirements.
- **QA Reviewers**
 - Reviewing technical requirements for quality and quality evaluation criteria.
 - As necessary, evaluating technical responses to solicitations for capability to meet quality requirements.
- **Procurement Staff**
 - Confirming that appropriate reviews have occurred before issuing solicitations or sole-source subcontracts.
 - Convening evaluation panels, if required.
 - Coordinating the evaluation of qualifications and technical responses to solicitations.
 - Maintaining documentation of required reviews and evaluations in the procurement file.

2.2.7 Procedures

The procedures listed below shall be followed when procuring technical services:

- **Identify Technical and Quality Reviewers:** The Work Order Manager, or designee, will identify qualified technical reviewers and schedule quality and technical reviews.
- **Develop the Technical and Quality Requirements:** The Work Order Manager, or designee, will complete the tasks listed below.
 - Prepare technical requirements by citing specific instructions; methods; operating procedures; drawings; specifications; codes; standards; regulations; any necessary licensing, permits, and restrictions; work-order-specific requirements; and quality program requirements.
 - List required submittals from the bidder or offeror to demonstrate technical and quality capability.
 - To the extent possible, specify the quality system elements for which the subcontractor is responsible and the means by which Parametrix will verify that technical and quality requirements are met.
- **Develop Technical and Quality Evaluation Criteria:** To the extent possible, the preparer will provide technical and quality evaluation criteria for inclusion in the solicitation or for documentation of a sole-source justification. Evaluation criteria will be appropriate to the solicitation type, and may contain technical and quality criteria that are presented as specific requirements that can be evaluated on an acceptable/not acceptable basis. RFPs will include weighted or point score evaluation criteria for ranking technical proposals and qualifications.
- **Technical and QA Review of Solicitation Technical Requirements:** The Work Order Manager will submit the SOW, specifications, technical evaluation criteria, and verification methods to designated reviewers before the documents and evidence of the reviews are forwarded to procurement staff. The reviewers will document their review comments and return them to the preparer to be addressed.
- **Technical Review:** The technical reviewer will complete the tasks listed below.
 - Verify that the methodology is appropriate and recommend any appropriate changes to the SOW/specifications to correct errors and enhance clarity.
 - Focus on detail of technical instructions and requirements so that the services performed will meet work order requirements.
 - Confirm appropriateness and completeness of evaluation criteria relevant to the scope of work.
- **QA Review:** The QA reviewer will complete the tasks listed below.
 - Consult the Quality Assurance Project Plan (QAPP) to determine quality requirements.
 - Incorporate specific quality requirements not already addressed in the solicitation or draft subcontract.
 - Document that review comments have been addressed.

- **Technical and Quality Evaluation of Responses to Solicitations:** The routine process for evaluating responses to solicitations includes various elements of responsibility as listed below.
 - The Work Order Manager will identify the review team for all responses. Reviewers should include technical, management, and procurement staff.
 - The procurement staff will distribute the technical responses to an RFP to the review team for evaluation of technical and quality requirements.
 - The review team will document technical and quality evaluations. Two signatures, or a clear statement that both technical and quality evaluations were performed, are required before final acceptance of a bid or proposal.
- **Verifying Quality/Acceptance of Services:** The Work Order Manager and/or QA staff are responsible for verifying that the chosen subcontractor meets all specifications, including reports and deliverables requirements as applicable.

2.2.8 Records

The following records will be maintained in the procurement files:

- Evidence of technical and QA review of technical requirements.
- Evidence of technical and quality evaluation of responses to technical requirements.
- Other documents required by current procurement procedures.

Project Managers may require that Work Order Managers maintain review/evaluation information as well.

2.2.9 References

References related to procuring technical services include:

- Applicable Federal Acquisition Regulations (FARs).
- Parametrix Purchasing Policy.

2.2.10 Exhibits

None.

2.3 CONTROL OF NONCONFORMING ITEMS

Prepared By:	_____	Date:	_____
	Bob Rosain		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

2.3.1 Title

Control of Nonconforming Items.

2.3.2 Purpose

To present the system for controlling nonconforming items at Parametrix.

2.3.3 Scope

This procedure applies to items that affect the quality of technical work, such as equipment, supplies, and instruments. Examples include M&TE, specialty construction materials, and treatment system components. This procedure does not apply to office supplies or equipment.

2.3.4 Related Procedures

Other procedures related to control of nonconforming items include:

- QP 2.1 – Procuring Measurement and Test Equipment.

2.3.5 Definitions

Nonconformance is a deficiency in characteristic, documentation, or procedure that renders the quality of an item unacceptable or indeterminate.

Government-Furnished Equipment refers to items that are either provided by the government or purchased with government funds.

Disposition is an action taken on a nonconforming item to return the item to service or discard the item.

Rework is a process by which an item is made to conform to the original requirements.

Repair is a process of restoring a nonconforming characteristic to a condition such that the capability is unimpaired, even though the item does not conform to the original requirements.

Use As Is can be defined as a disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

2.3.6 Responsibilities

Responsibilities for control of nonconforming items include:

- **Personnel**
 - Identifying nonconforming items, segregating the items, and reporting the nonconformance to the Work Order QA Manager.
 - If required for the project, labeling or tagging the items and documenting the nonconformance conditions.
- **Work Order Manager**
 - Implementing the control on nonconformance procedure.

2.3.7 Procedures

For control of nonconforming items, the following procedures shall be followed:

- **Identify the Nonconforming Item:** Nonconformance may be discovered through inspection, field complaints, testing, or service calls. For potential nonconformances identified during receipt inspection, the receiver notifies the requisitioner, who determines if the item is nonconforming.
- **Prevent Inadvertent Use:** The person identifying a nonconforming item will ensure that it is immediately segregated and/or labeled or tagged so it will not be inadvertently used.
- **Initiate the Nonconformance Report:** The person identifying a nonconformance will initiate a nonconformance report that will be distributed as listed below.
 - Parametrix procurement staff, for newly purchased or procured items.
 - Work Order QA Manager, for M&TE, project supplies, equipment, and materials.
- **Evaluate the Nonconforming Item:** To determine the appropriate disposition of nonconforming items, the appropriate technical staff in consultation with the Work Order QA Manager will assess the item and alternatives for final disposition. Allowable dispositions include rework, repair, return to vendor, use as is, or discard.
- **Dispositions Requiring Verification:** Dispositions that require verification are listed below.
 - Rework: A reworked item requires verification to document that the original requirements have been met. The verification may be limited to the affected parts or subsystem. The person or firm performing the rework will be identified in the nonconformance report, and the individual performing the verification will sign the nonconformance report.
 - Repair: A repaired item does not conform to all original requirements but is suitable for its intended use. A repaired item also requires verification by an appropriately qualified individual to determine if the repair is adequate to make the item suitable for its intended use. The verification may be limited to the affected parts or subsystem. The person or firm performing the repair will be identified in the nonconformance report, and the individual performing verification will sign the nonconformance report.

- **Dispositions Requiring Authorization:** Dispositions that require authorization are listed below.
 - Return to Vendor: If a newly procured nonconforming item is to be returned to the vendor, the nonconformance report will be forwarded to the procurement staff, who will obtain a return authorization number from the vendor and will record it on the nonconformance report.
 - Use As Is: The decision to use a nonconforming item may be made if it can be established that the item is satisfactory for its intended use. The decision to use as is must be authorized by the individual responsible for establishing the task-order-specific requirements and must be documented on the nonconformance report.
 - Discard: Nonconforming items may only be discarded in accordance with the Federal Acquisition Regulations and appropriate Parametrix property control procedure. The authorization will be documented on the nonconformance report.

2.3.8 Records

Completed nonconformance reports, or equivalents, and additional disposition documentation, if required, will be maintained as follows:

- Records for returned, newly procured items will be maintained by procurement staff.
- Records for M&TE, project supplies, equipment, and materials will be maintained by the Work Order Manager.

2.3.9 References

None.

2.3.10 Exhibits

None.

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3. DOCUMENTS AND RECORDS

3.1 DOCUMENT CONTROL

Prepared By:	_____	Date:	_____
	Brenda Holt		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

3.1.1 Title

Document Control.

3.1.2 Purpose

To describe the document control procedures at Parametrix.

3.1.3 Scope

This procedure applies to all technical standard operating procedures, quality procedures, and contract deliverables.

3.1.4 Related Procedures

Other procedures related to document control include:

- QP 3.2 – Technical Document Review.
- QP 3.3 – Quality Assurance Review.
- QP 3.4 – Records Control.

3.1.5 Definitions

Documents are information in any medium, including paper copy, electronic files, computer disks or other computer storage media, tapes, audio or video tapes, photographs, and overhead or graphic presentations.

Document control is the process of ensuring that documents, including revisions, are reviewed for quality, approved for release by authorized personnel, and properly distributed.

Controlled document refers to a document that requires specific tracking of each copy. Such documents will be identified in scopes of work.

3.1.6 Responsibilities

The following lists specific responsibilities for preparing, reviewing, approving, and issuing documents:

- **Project/Deputy Project Manager**
 - Assessing the adequacy and completeness of document reviews.
 - Defining generic distribution lists for contract and work order documents.
 - Approving and issuing documents.
- **Work Order Managers and Work Order QA Managers**
 - Directing the preparation and production of work order documents.
 - Assigning appropriate staff to perform management, quality, and technical assessment and review of each document.
 - Scheduling the required reviews, assigning qualified reviewers, working with reviewers to resolve comments, and revising documents as necessary to address comments.
 - Reviewing all work order documents for consistency with the scope of work and the intended use of the document. Primary authors are responsible for developing outlines, researching existing information, compiling and reducing document content, preparing text and graphics, technical editing, document production, and review.
- **Reviewers**
 - Reviewers are responsible for following procedures appropriate to the type of review, as defined by the Work Order Manager and Work Order QA Manager (e.g., QP 3.2, Technical Document Review; QP 3.3, Quality Assurance Review; and the corporate HSP).

3.1.7 Procedures

The following outlines the QA review of document preparation and control:

- **Document Format Requirements:** Format of all documents will include document identification as described below.
 - Document Identification: Each document will be clearly identified with a footer on each page giving the section number, date, and appropriate pagination. The footer also identifies the file location (e.g., server, file directory). If required by the contract or Project/Deputy Project Manager, each document will also be assigned a revision number or alphanumeric identifier number (e.g., a document control number) and/or entered in an index of project documents.
- **Document Preparation, Review, Approval, and Issuance:** Parametrix will prepare contract documents consistent with the procedures described below.
 - Document Preparation: All documents will be prepared in accordance with the Parametrix Document Standards Manual. Work Order Managers and the primary author will develop an outline and a review schedule and, with the Work Order QA Manager, assign document reviewers.

- **Document Review:** Document reviewers are responsible for ensuring that they understand the review requirements and procedures. The document reviewer will work with the Work Order Manager or preparer to resolve comments regarding the document, and the Work Order Manager or preparer will revise the document as necessary. Reviewers are responsible for documenting their reviews.
- **Document Approval:** All contract documents will be approved as listed below.
 - Reports: Project/Deputy Project Manager/Work Order Managers/Work Order QA Managers/Primary Author.
 - Correspondence: Work Order Managers.
 - Memos: Work Order Managers/Work Order QA Managers.
- **Document Issuance:** The issuer will check to determine if controlled distribution is required and ensure that the elements listed below are complete.
 - The document is complete and legible.
 - Required approvals have been obtained.
 - The distribution list is appropriate for the type of document.
 - Copies for distribution are complete and legible.
- **Document Distribution:** The Work Order Manager will determine document distribution requirements (including hard copy and electronic files). Each document will be filed in accordance with QP 3.4, Records Control.
- **Document Revisions:** Documents may be revised to incorporate comments; to reflect changes in scope of the project, technologies, or methods; or to present changes in project funding or schedule. Revisions (including addenda) to documents generally require the same types and levels of review as original documents.

Work Order Managers, with the Project/Deputy Project Manager and Work Order QA Manager, should judge the nature and extent of the revision to determine the appropriate review needs.

The review team and primary author shall document that revisions have been addressed.
- **Deviations/Variance:** The QA Officer or the Project/Deputy Project Manager may authorize deviations from or variances to this QP.

3.1.8 Treatment of Confidential Business Information (CBI)

CBI may be disclosed to Parametrix as necessary to carry out the work required under the contract. Parametrix agrees to use CBI only under the following conditions:

- Parametrix will use CBI only for the purposes of carrying out the work required by the contract.
- Parametrix will return to the contracting officer (CO) all copies of the information and any abstracts or excerpts therefrom, upon request by the CO, whenever the information is no longer required by Parametrix for the performance of the work required by the contract, or upon completion of the contract.

- Parametrix will obtain a written agreement to honor the above limitations from each employee who will have access to the information before that employee is allowed access to the information.
- Parametrix will not disclose the information to anyone other than employees with signed agreements.
- Parametrix will not use any CBI obtained during performance hereunder to compete with any business to which the CBI relates.
- Parametrix will also obtain the written consent of the Client prior to entering into any subcontract that will involve the disclosure of CBI by Parametrix to the subcontractor. Parametrix will include all of the above conditions in all subcontracts awarded pursuant to this contract that require furnishing CBI to the subcontractor.

3.1.9 Records

The following records will be maintained for each document issued:

- Copy of the document.
- Distribution list.
- Review and approval documentation.

3.1.10 References

Other references regarding document control include:

- Parametrix Document Standards Manual.
- Parametrix AutoCAD and GIS Standards Manual.

3.1.11 Exhibits

None.

3.2 TECHNICAL DOCUMENT REVIEW

Prepared By:	_____	Date:	_____
	Bob Rosain		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

3.2.1 Title

Technical Document Review.

3.2.2 Purpose

To describe the internal technical review system at Parametrix for technical documents.

3.2.3 Scope

This procedure applies to contract documents containing technical information.

3.2.4 Related Procedures

Other procedures related to technical document review include:

- QP 3.1 – Document Control.
- QP 3.3 – Quality Assurance Review.

3.2.5 Definitions

A Technical Document is defined as technical information in any medium prepared in support of the Contract and/or the Work Order Work Plan (refer to QP 3.1).

A Technical Document Review is the process of checking the document for technical accuracy, accomplishment of project objectives, and clarity of presentation.

Document Revision refers to required changes or updates to existing documents in response to technical reviewer comments. Revised documents require technical review.

3.2.6 Responsibilities

Responsibilities for personnel reviewing technical documents include:

- **QA Officer:** Establishing review procedures and monitoring compliance.
- **Work Order Managers:** Working with the Work Order QA Managers and primary authors, selecting technical reviewers, and scheduling all reviews.
- **Technical Reviewers:** Thorough and timely reviews of the technical content of documents.

- **Work Order QA Manager:** Monitoring technical reviews and associated documentation.

3.2.7 Procedures

The following procedures shall be completed when technically reviewing documents:

- **Reviewer Selection:** The Work Order Manager will identify and select technical reviewer(s) who are independent of the document to be reviewed. When appropriate, multiple reviewers will be identified for the entire document or for certain sections of the document.
- **Scheduling and Planning:** The Work Order Manager will develop a schedule for technical reviews. The schedule, review roles and responsibilities, and budget allocation will be presented in work order planning documents.
- **Reviewer Concurrence:** When selected, technical reviewers must concur that they are qualified to perform the review and that they will complete the review according to the required schedule.
- **Concurrent Review with the Client (over-the-shoulder review):** When requested by the Client, the Work Order Manager may forward the draft document, or portions of the document, to the Client for concurrent review.

In these cases, each electronic and/or paper page will be marked in a manner that clearly identifies the document as a preliminary document or draft. The document will be clearly marked as a working draft that is subject to revision following completion of the review process.

- **Documentation Requirements:** Each reviewer is responsible for documenting their review and ensuring that appropriate documentation is placed in the work order file. Primary authors are responsible for documenting their response to review documents.
- **Initiating the Technical Review:** The Work Order Manager will discuss review requirements with each reviewer and specifically address or define the items listed below.
 - The work order scope and objectives (statement of work may be attached).
 - The budget and schedule constraints.
 - The standards or requirements for computer system review and testing.
 - Client expectations for use of the document and its technical information.

The Work Order Manager will submit the draft and relevant background materials to the reviewer.

- **Technical Review:** The technical reviewer will complete all items as noted below.
 - Meet with the Work Order Manager and develop a mutual understanding of the review requirements.
 - Check the document for technical accuracy, consistency with the scope of work, and clarity of presentation. The check for technical accuracy includes reviewing material in the document for correctness of concepts, cost estimates, recommendations, and conclusions.

- Check for evidence that quality control checks of equations and calculations, reference citations, and tables or figures have been performed. If no evidence of earlier checks is provided, the technical reviewer should spot-check the accuracy of equations and calculations, reference citations, and tables and figures.
- Note all comments directly on the draft.
- Document whether a follow-up technical review is required.
- Contact the Work Order QA Manager and primary author to discuss significant questions or comments.
- Document for the record that the review was completed.
- Return the review package to the primary author.
- **Comment Review and Resolution:** The Work Order Manager will review the comments. The primary author and technical reviewer should be contacted if clarification is needed. Comment review and resolution will be completed as determined below.
 - Resolution When Follow-up Review is Not Requested: If the Work Order Manager accepts the comments made by the technical reviewer, the Work Order Manager will see that the document is revised according to the comments.
 - Requirements for Follow-up Review: If the technical reviewer has requested follow-up review, the document will be revised to address the comments and returned to the reviewer for supplemental review.
 - Acceptance of Revisions: When the technical reviewer concurs that the document has been adequately revised, the technical reviewer will sign the document for release to the Work Order QA Manager and Work Order Manager.
 - Problem Resolution: If the Work Order Manager and technical reviewer cannot agree on a resolution to comments, the Project/Deputy Project Manager will be contacted to facilitate a resolution. If necessary, the Work Order QA Manager or the QA Officer may be contacted to assist with comment resolution. Final resolution will be documented in a memorandum that discusses how the comment was handled and resolved.
- **Closure:** When all technical reviews are completed and comments resolved, the Work Order Manager will issue the document for management and quality reviews.
- **Document Revisions:** Technical documents may be revised to incorporate client or other stakeholder comments; to reflect changes in scope of the project, technologies, or methods; or to present changes in project funding or schedule.

Revisions (including addenda) to existing, issued documents generally require the same level of review as original documents. However, the Work Order QA Manager should judge the nature and extent of the revision to determine the appropriate review needs.

- **Review Follow-Through:** The Work Order Manager and technical reviewer are encouraged to discuss “lessons learned” from the review process to improve the effectiveness of the technical review procedure and the quality of technical documents.

3.2.8 Records

Internal review drafts will not be placed in the project files. Internal review drafts, as applicable, may be discarded at the time the document is issued. Internal review drafts must be discarded at the time the client or other recipient accepts or approves the document.

The following records will be maintained in the project files:

- Each document version issued to the client.
- Documentation of reviews and responses to review comments.

3.2.9 References

None.

3.2.10 Exhibits

None.

3.3 QUALITY ASSURANCE REVIEW

Prepared By: _____ Date: _____
Bob Rosain

Reviewed By: _____ Date: _____
Brad Hermanson, QA Officer

Approved By: _____ Date: _____
William Stubblefield, Project Manager

3.3.1 Title

Quality Assurance Review.

3.3.2 Purpose

To define the QA review requirements at Parametrix.

3.3.3 Scope

This procedure applies to the following document types prepared by Parametrix or its subcontractors:

- Work Order Work Plans.
- Documents prepared at the direction of the Client.
- Technical standard operating procedures (SOPs).

Documents to procure technical services require QA review according to QP 2.2.

3.3.4 Related Procedures

Other procedures related to a quality assurance review include:

- QP 2.2 – Procuring Technical Services.
- QP 3.1 – Document Control.
- QP 3.2 – Technical Document Review.

3.3.5 Definitions

QA Review is defined as an independent review of a document by an authorized QA Reviewer to ensure that the document meets any specific QA and quality control (QC) requirements. QA review does not duplicate technical review; it checks on quality assurance/quality control (QA/QC) requirements specific to the type of document.

The Scope of Work is part of the Work Order Work Plan that defines work order goals, objectives, assumptions, and costs. The Work Order Work Plan and scope of work are generated through negotiations with the client.

The Work Order Management Plan presents technical and management approaches at Parametrix for accomplishing the scope of work requirements in the Work Order Work Plan.

Technical Documents are documents that present quantitative data and information generated during work order work, and may include QAPPs, Health and Safety Plans (HSPs), and data reports.

3.3.6 Responsibilities

Quality assurance responsibilities include:

- **Work Order Managers:** Work Order Managers, in consultation with the Work Order QA Managers, are responsible for scheduling sufficient time for QA reviews, providing copies of technical review comments to the QA reviewer, resolving review comments with the QA reviewer, and maintaining required documentation.
- **QA Reviewers:** QA reviewers are responsible for a timely and independent review of documents according to Parametrix requirements and standards. QA reviewers are also responsible for cooperating during comment resolution and completing appropriate review forms.
- **QA Officer:** The QA Officer is responsible for training and authorizing individual QA reviewers in the QA review of specific document types.

3.3.7 Procedures

The QA review procedures are listed as follows:

- **Reviewer Qualification:** The QA Officer authorizes QA staff members who have completed training for QA review of individual categories of documents.
- **Scheduling the QA Review:** The Work Order Manager will schedule reviews with the QA reviewer. The Work Order Manager will forward a copy of the draft document and comments from the technical reviewer(s) to the QA reviewer.
- **Concurrent Review with the Client (over-the-shoulder review):** When requested by the Client, the Work Order Manager may forward the draft document or portions of the document to the Client for concurrent review. The Work Order Manager or document author may work directly with the Client in developing the final document.

In these cases, each electronic and/or paper page will be marked in a manner that clearly identifies the document as a preliminary or draft document. The document will be clearly marked as a working draft that is subject to revisions following completion of the review process.

- **Conducting the QA Review:** Several steps in the QA review process are applicable to all document types and are discussed immediately below. In performing the review, the QA reviewer shall:
 - Check the appropriate Parametrix corporate or contract-specific documents for QA requirements.
 - Discuss questions or comments regarding review requirements with the Work Order Manager and/or primary author.
 - Note all comments directly on the draft.
 - Document the review and whether or not a follow-up QA review is required.

- At the Work Order Manager's request, spot-check any table of contents against the body of the document for accuracy of page numbers and figure or table titles, and check the document's appearance and copy quality.

When the QA review is complete, the QA reviewer will sign and return the marked-up review draft to the Work Order Manager and work order file.

- **Comment Review and Resolution:** The Work Order Manager and the author will review the comments. The author, technical reviewer, and QA reviewer should be contacted if clarification is needed. Comment review and resolution will be completed as determined below.
 - Resolution When Follow-up Review is Not Requested: If the Work Order Manager accepts the comments made by the QA reviewer, the Work Order Manager will see that the document is revised according to the comments.
 - Requirements for Follow-up Review: If the QA reviewer has requested follow-up review, the document is revised to address the comments and returned to the reviewer for supplemental review.
 - Acceptance of Revisions: When the QA reviewer concurs that the document has been adequately revised, the QA reviewer will sign the document for release to the Work Order QA Manager and Work Order Manager.
 - Problem Resolution: If the Work Order Manager and QA reviewer cannot agree on a resolution to comments, the Project/Deputy Project Manager will be contacted to facilitate a resolution. If necessary, the Work Order QA Manager or the QA Officer may be contacted to assist with comment resolution. Final resolution will be documented in a memorandum that discusses how the comment was handled and resolved.
- **Closure:** When all QA reviews are completed and comments resolved, the Work Order Manager will issue the document.
- **Document Revisions:** Technical documents may be revised to incorporate comments; to reflect changes in scope of the project, technologies, or methods; or to present changes in project funding or schedule.

Revisions (including addenda) to existing, issued documents generally require the same level of review as original documents. However, the Work Order QA Manager should judge the nature and extent of the revision to determine the appropriate review needs.
- **Review Follow-Through:** The Work Order Manager and QA reviewer are encouraged to discuss "lessons learned" from the review process to improve the effectiveness of the technical review procedure and the quality of technical documents.

3.3.8 Records

Internal review drafts will not be placed in the work order files. Internal review drafts may be discarded at the time the final document is issued. The following records will be maintained in the work order files:

- Technical/QA Review Form, or equivalent.
- Review comments and evidence of resolution, if applicable.

3.3.9 References

None.

3.3.10 Exhibits

None.

3.4 RECORDS CONTROL

Prepared By: _____ Date: _____
Brenda Holt

Reviewed By: _____ Date: _____
Brad Hermanson, QA Officer

Approved By: _____ Date: _____
William Stubblefield, Project Manager

3.4.1 Title

Records Control.

3.4.2 Purpose

To describe the Parametrix records control system.

3.4.3 Scope

This procedure applies to the receipt, filing, access, indexing, retrieval, and storage of documents and records, and presents several options for the various aspects of records control.

This procedure does not address confidential, financial, contractual, or classified documents. These types of documents are handled in accordance with Parametrix procedures.

3.4.4 Related Procedures

Other procedures related to records control include:

- QP 3.1 – Document Control.

3.4.5 Definitions

A Document is technical information in any medium that describes, defines, specifies, reports, certifies, requires, or provides data or results pertaining to the Client Contract or work orders.

A Record is a completed, validated document and/or other material that provides objective evidence of an item or process affecting quality. A document containing objective information can become a record once it is complete and identified as a record. Examples include work order work plans, deliverables, reports, correspondence, field notes, laboratory data, and other QA/QC documents. Documents that provide supporting information may also be considered as records.

Records Control is the process of identifying records and providing ready retrieval, storage, protection, and disposition of records.

Records Validation refers to the process of checking a document to ensure that it is complete, legible, and appropriate to be a record.

3.4.6 Responsibilities

Responsibilities for record control include:

- **Project/Deputy Project Manager:** The Project/Deputy Project Manager is responsible for defining the level of records control required, developing records control guidance and procedures, training Work Order Managers in the use of the records control system, and ensuring that the procedures are implemented. The Project/Deputy Project Manager may assign some or all of these activities to other individuals.
- **Contract and/or Work Order Administrative Assistants:** The Contract and/or Work Order Administrative Assistants are responsible for maintaining the official contract and/or work order files. These individuals are responsible for implementing a formal records control system.
- **Work Order Manager:** The Work Order Manager is responsible for working with Administrative Assistants to ensure that records are handled in accordance with the records control requirements.

3.4.7 Procedures

The procedures listed below provide several options for records control. Individual options may be invoked by the Project or Work Order Manager, as appropriate.

- **Defining Records Control Requirements:** The Project/Deputy Project Manager should establish policies governing records control for the contract and all associated work orders. For certain work orders, the Project Manager may note that formal records control is not required. Regardless, work order files should be neat, orderly, and essentially complete.
- **Identifying the Work Order Administrative Assistant:** The Work Order Manager should name an individual as having primary responsibility for maintaining the work order files. This individual may perform other duties under the work order.
- **Developing the File Structure:** Depending upon the requirements of the scope of work, or as otherwise directed by the Project/Deputy Project Manager, all work on the contract will follow the contract records management procedures (Exhibit 3.1). This procedure establishes an electronic and hard copy file structure and file management procedures.
- **Records Identification:** Individual documents are identified by title, date, and work order number.
- **Using Records:** The Parametrix records system utilizes a file index. For hard copy files, the use of "out cards" as temporary place markers is used. Access to e-files allows only one user at a time. If another user attempts to access the file while in use, the first user's name is indicated and the second user may only make an electronic "copy" of the original file.
- **Distributing Records:** Internally generated documents will be issued and distributed according to the procedures described in QP 3.1, Document Control. External documents requiring incorporation into the records control system should be forwarded to the Administrative Assistant by the recipient.

- **Receipt of Records:** All documents that are designated as potential records will be received by the assigned Administrative Assistant. This individual will perform the following activities:
 - Validate the Record: The document will be checked to ensure that it is complete, legible, and appropriate to be a record. This process includes:
 - Inspecting the document for completeness.
 - Inspecting the document for legibility of copy(ies).
 - Contacting the originator of the document to rectify any validation problems.
 - If required, marking the record to indicate validation. This can be accomplished by affixing the Administrative Assistant's initials, marking with a rubber stamp such as "file copy," or other suitable means.
 - File the Record: The Administrative Assistant should promptly file the record in accordance with the established file structure.
 - Use of Records in the Records Control System:
 - *Access:* In general, only staff working on a particular contract will have access to the documents for that contract. If required by the Project Manager, a list of authorized personnel for each contract will be posted.
 - *Checkout Log:* The Administrative Assistant will develop and maintain a checkout log of the checkout and return of documents to the records control system. This log should be electronic, and in a software tool that allows easy searching and sorting (e.g., Microsoft® Excel or Access). It should include, at a minimum: document title and revision number, copy number (if applicable), person checking out the document, date checked out, and date checked back in.
 - *Retrieval and Checkout:* Hard copy documents can be retrieved by searching the log and/or physical files and checking out the documents as appropriate. The document user should notify the Administrative Assistant, and/or place a "checkout" card in the file if a record is removed from the file.
 - *Record Re-filing:* When the user of a record is finished with the record, the document should be promptly returned to the Administrative Assistant for filing. If appropriate for the contract, the Administrative Assistant will annotate the checkout log or remove the checkout card from the files to indicate that the record has been returned.
- **Retention:** Retention and ultimate disposition of records will be determined in consultation with the Client.

3.4.8 Records

Records retention is outlined as follows:

- **Record Storage Requirements:** Records will be stored in the Parametrix office responsible for performing the contract activities.
- **Record Preservation:** Records will be stored in enclosed file cabinets, on document storage shelving, or in file storage boxes.

- **Facilities:** Records will be stored in facilities that reduce the risk of damage or destruction, including natural disasters such as floods or fires, environmental conditions such as high and low temperatures, humidity, and pests.
- **Disposition:** Record disposition includes transferring records to the Client and discarding records. At the completion of the agreed-upon retention period, records will be transferred, discarded, or the retention period extended.

Records to be transferred will be inventoried before transfer, if requested or required by the Project/Deputy Project Manager. The Client, or his/her representative, should sign a receipt for the records that references or includes the inventory list. This receipt and inventory, if generated, will be maintained by Parametrix as evidence of the transfer.

Records to be discarded will also be inventoried, if requested or required by the Project Manager. The inventory list will be reviewed by the Project/Deputy Project Manager, who will authorize, in writing, the disposition of those records. The authorization to discard records and the inventory list will be maintained by Parametrix.

3.4.9 References

None.

3.4.10 Exhibits

The following exhibit is included with the records control quality procedure:

- Exhibit 3.1 – Contract Records Management System.

EXHIBIT 3.1

Contract Records Management System

Records Management

There are two types of files under this contract: electronic and hard copy. Electronic files for all contract and work order deliverables reside on the Parametrix server. Hard copy files are office-centric and are set up and maintained by the office the work order is managed from. If there is no contract requirement to maintain paper copies of electronic deliverables, records will be kept for 10 years after the closeout of the Client contract. Hard copy files might typically contain subconsultant agreements, field notes, photos and other paper matter that supports electronic deliverables. Although it can be changed on a case-by-case basis, the filing structure for both hard copy and electronic files should generally follow the structure defined below. The Work Order Manager and Project Coordinator will determine the level of detail needed for each folder.

Task 01 PP PROJECT PLANNING*

1.1 CONTRACT DOCUMENTATION*

- 1.1.1 Scoping and Pre-Task Order Documents (SOW, meeting minutes)*
- 1.1.2 Contract & Modifications*
- 1.1.3 Conflict of Interest*
- 1.1.4 Work Plan & Amendments (Work Plan includes scope, schedule & budget)*
 - a. Work Plan*
 - Draft
 - Final
 - b. WPA#1
 - Draft
 - Final
- 1.1.5 Work Order Management Plan (aka PMP)
- 1.1.6 Subconsultant Authorizations (if applicable)
- 1.1.7 Procurement (if applicable)

Optional Additional Subtasks:

Schedule Updates (this is not a copy from the scope)

1.2 FINANCIAL*

- 1.2.1 Monthly Reports (includes invoice, progress reports, and any other associated correspondence)*
- 1.2.2 Pre-bills*
- 1.2.3 85% Funding Notices*

Optional Additional Subtasks:

Budget Tracking
Earned Value
Variance/BST Reports
Weekly Reports

1.3 GENERAL CORRESPONDENCE*

(Correspondence will be filed with the work element it is associated with. This is a placeholder for general correspondence not related to a specific task in the work breakdown structure [WBS].)

1.4 SUPPORT DOCUMENTS*

Possible Subtasks:

Project File Index

Task 02 XX WBS TASK NAME

Remaining structure is tied to the work plan WBS. Each task will have a folder and can have any level of detail needed to keep the materials organized. Some tasks will need nothing more than a single folder, others will require itemized lists.

**NOTE: The required minimum categories for work order files on this contract.*

There is flexibility to expand the above structure. The Work Order Manager and Administrative Assistant will decide if there are additional required sections to be included in the structure of the work order files. Work order files are administered by the work order technical support staff.

Secured electronic folders can also be set up for privileged and confidential documents. The Work Order Manager and Administrative Assistant will need to work with the Parametrix Information Technology staff to create secured folders if this is necessary.

Records Management Database

The records management database is updated to include the new work order information as follows:

- Work Order Manager Name.
- Work Order Number.
- Work Order Name.
- Start/End Dates.
- File Structure.

After information is entered into the database, the index report will be printed and placed on the outside of the work order file in a clear sleeve.

Records management databases are currently set up and maintained as Microsoft Access database files. The database contains all current and archived file information.

Hard Copy Photographs

All photographs should be labeled to indicate the assignment for which they were taken. Below are the two examples of how the photos should be labeled (on the rear of the photo).

Name:	PM:
Job #:	Date Taken:
Photo #:	Roll #:
Description:	

Name:
PM:
Job #:
Date Taken:
Photo #:
Roll #:

Digital Photographs

Digital photos are processed as follows:

- Initial download will be to the appropriate electronic work order folder.
- Photos should be compressed. Two separate electronic folders will be created: ORIGINALS and COMPRESSED.
- The ORIGINAL folder will be transferred onto two CDs. One CD will be kept in the work order file, and the second CD will be sent to off-site storage or to a fireproof vault.
- Each CD will be labeled with the client name, work order number, work order name, and date.
- Compressed photographs will be copied to CD with the rest of the work-order-related information when the job is completed and ready for archive.

Work Order File Archiving Procedures

The file structure for all work orders is recorded into a database by work order number so that files can be easily located when needed. This database is a detailed inventory of how the work order file is set up (i.e., the sections of the work order file) and any other information that will be helpful in locating this particular file (i.e., Work Order Manager's name, work order number, work order name, start/end dates, etc.).

Work order files are archived as follows and as appropriate:

- Once a year.
- When space constraints arise.
- When the Work Order Manager indicates that a work order has been closed.

The Project Manager approves archival of all information before it is sent to archive. The Work Order Manager designates the compiling of the work order files ready for archive. The information is boxed and the database is updated to indicate that the file is now in archive. The work order files are shipped off-site to a "controlled facility." If information is requested to be retrieved, the controlled facility will be notified and the documents will be sent within 24 hours.

Electronic File Archiving Procedures

Electronic files are archived when necessary, according to standard office protocol. All archived electronic files should be transferred to a CD.

Three CDs of the archive files should be made: 1) one for the Work Order Office Library, 2) one for the Word Processing Department, and 3) one for backup (sent off-site or to the fireproof safe on site). If requested, a CD will be created for the Client.

Retention of Files

Per contract requirements.

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4. COMPUTER HARDWARE AND SOFTWARE

4.1 CONTROL OF COMPUTER HARDWARE AND SOFTWARE

Prepared By:	_____	Date:	_____
	Robin McManus		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

4.1.1 Title

Control of Computer Hardware and Software.

4.1.2 Purpose

To describe the system for controlling computer hardware and software at Parametrix to ensure proper operation and compatibility.

4.1.3 Scope

This procedure applies to commercially purchased computer hardware and software applications used to design environmental systems, or to perform computations or database operations on environmental data.

This quality procedure does not apply to computer hardware and software that is integral to measurement and testing equipment or that is used for word processing, accounting, marketing, human resources, staff scheduling, or other general office tasks. Software development is addressed in QP 4.2.

4.1.4 Related Procedures

Other procedures related to control of computer hardware and software include:

- QP 4.2 – Control of Developed Software.

4.1.5 Definitions

Computer Hardware is any electronic or physical part of the computer and peripherals. This includes, but is not limited to, microprocessor, power supply, memory, drives, keyboard, monitor, mouse, printer, and plotter.

Operating System is the basic instruction set that controls how the computer reads and/or uses application software and peripheral devices. Examples of operating systems are DOS, Windows, Mac OS, and Linux.

Application Software and Databases are the purchased or developed computer code that enables the user to perform work with the computer. Examples of purchased application software are BST Enterprise, ARC/INFO, AutoCAD, Sequel, Word, Excel, and Access. Examples of Parametrix-developed software are POWER, UCL, and Sales Plan.

Computer System is an automatic data processing equipment consisting of processor, local storage device, input and output devices, operating system, application software(s), printing and plotting connections, local and wide area network connectivity, and access to the Internet.

Configuration is the combination of hardware, operating system, and application software for a particular computer system.

4.1.6 Responsibilities

Specific responsibilities for providing, maintaining, and operating Parametrix computer systems are as follows:

- **Parametrix Information Technology Division (ITD)**
 - Establishing and maintaining company-wide hardware, software, and configuration standards.
 - Design and/or procurement of all hardware and software.
 - Testing and implementation of software designed by ITD.
 - Maintaining all Parametrix computer systems.
 - Documenting computer system configurations.
- **Computer Users**
 - Ensuring that testing is performed when required, and is documented.
 - Adequately checking the accuracy of user-generated formulas and computations.
 - Ensuring that adequate back-ups of work products are maintained.
 - Reporting any hardware or software problems to the local office ITD staff professional.

4.1.7 Procedures

Procedures for control of computer hardware and software include:

- **Procurement:** Purchasing of all hardware and software will be done by the ITD in accordance with the procedures defined in the Parametrix Purchasing Policy.
- **Initial Testing:** Upon initial installation of a computer system, the system configuration will be documented. The system will be tested to verify that the hardware, operating system, and applications software are operating properly. The results of the testing will be documented.

- **Modifications:** Before any change is made to the computer system, the consequence of that modification will be considered. After any modification to the computer system or configuration, the system will be retested to verify proper operation. This testing may be limited to the affected parts of the system. The system configuration documentation will be updated to reflect the modification, and the results of any testing will be documented.
- **Checking Calculations and Formulas:** When the computer user is writing formulas to perform calculations, an alternate calculation method should also be used initially to verify the accuracy of the formulas.

4.1.8 Records

The following records will be kept readily accessible:

- Up-to-date configuration documentation.
- Results of initial testing and any retesting.

4.1.9 References

Other documentation regarding control of computer hardware and software includes:

- Parametrix Purchasing Policy.

4.1.10 Exhibits

None.

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4.2 CONTROL OF DEVELOPED SOFTWARE

Prepared By:	_____	Date:	_____
	Robin McManus		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

4.2.1 Title

Control of Developed Software.

4.2.2 Purpose

To describe the system and responsibilities for control of in-house developed software at Parametrix to ensure proper validation, operation, and documentation.

4.2.3 Scope

This procedure applies to computer software development and maintenance activities for technical work on the Client contracts. It does not apply to software used for other Parametrix projects or for word processing, accounting, marketing, human resources, staff scheduling, or other general office tasks. This procedure does not apply to use of commercially available or client-furnished software.

4.2.4 Relate Procedures

Other procedures related to control of developed software include:

- QP 4.1 – Control of Computer Hardware and Software.

4.2.5 Definitions

Developed Software is computer software that is created or modified by Parametrix for technical work under a Client contract.

Documentation includes user manuals, functional specifications, flow charts, internal program documentation, online manuals, and support information associated with the developed software.

Software Standards are published documents specifying the computer software development methods and/or technical and performance requirements of the developed software.

4.2.6 Responsibilities

Specific responsibilities for the development, documentation, and testing of in-house software are as follows:

- **Project Manager or Work Order Manager**
 - Determining, in consultation with the Client and Parametrix ITD staff, the appropriate software standard (if any) to follow.
 - Determining in consultation with the Client and Parametrix ITD staff the documentation that will be furnished with the software.
 - Ensuring that reviews and testing are performed when required and are documented.
 - Ensuring that required records are maintained.
- **Parametrix ITD Staff**
 - Following the designated standards for the software development project.
 - Development, testing, and implementation of the software.
 - Conducting periodic verifications of the work to ensure that the software operates properly.

4.2.7 Procedures

The published software standard (if any) to be followed will be determined in consultation with the Client and Parametrix ITD staff. Based on the nature and criticality of the software task, the entire published standard, a subset of the standard, or no standard will apply. The following elements will be addressed as a minimum for each software development or maintenance task:

- **Documentation:** Software documentation will be evaluated for conformance with requirements and/or standards prior to software release. In the absence of documentation requirements, minimum documentation will be developed so that the Client and developer have a firm understanding of what is being developed. The minimum documentation will include the items listed below.
 - System concept paper (overview).
 - Functional requirements document.
 - System preliminary design and final design.
 - Guide for end users.
 - System documentation, including data dictionary and revision (version) numbers for each release of software.
- **Testing and Review:** Regularly scheduled testing and review will be done to verify that the requirements detailed in the functional requirements document are satisfied. Testing may include a walk-through at each step of the design and development process to ensure that what is developed meets the published requirements. The testing protocol and the results of the testing will be documented by the person conducting the tests. The test results will be reviewed by the Project Manager or

Work Order Manager and software development staff to plan and implement corrections, if required.

- **Change Control:** Project-specific change control procedures will be used to ensure that proposed modifications are reviewed and approved.

4.2.8 Records

Software, documentation, and test results will be stored for the period of time specified in the contract. This includes "as delivered" versions of the software as well as final deliverables.

4.2.9 References

None.

4.2.10 Exhibits

None.

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5. CONTROL OF WORK PROCESSES

5.1 PREPARATION OF QUALITY PROCEDURES

Prepared By:	_____	Date:	_____
	Linda R. J. Logan, PhD		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

5.1.1 Title

Preparation of Quality Procedures.

5.1.2 Purpose

To provide guidance on, and assign responsibilities for, the preparation of technical and quality procedures.

5.1.3 Scope

This procedure applies to the development of procedures initiated for Parametrix work such as Technical SOPs and QPs.

This procedure does not apply to the development of planning documents such as work plans, QAPPs, field sampling and analysis plans, HSPs, or administrative procedures.

5.1.4 Related Procedures

Other procedures related to the preparation of technical and quality procedures include:

- QP 3.1 – Document Control.
- QP 3.2 – Technical Document Review.

5.1.5 Definitions

Procedure is a written document that provides step-by-step instructions for tasks to be performed correctly and consistently. Procedures are written and reviewed by qualified personnel.

Quality Procedure (QP) is a procedure that specifies the steps necessary to implement elements of the quality program.

Format is the organization, content, and visual presentation of a quality procedure or technical report.

5.1.6 Responsibilities

Responsibilities for preparation, review, approval, and issuance of procedures are given in QP 3.1, Document Control.

5.1.7 Procedures

Procedures for developing technical and quality procedures shall include:

- **Determine Format:** The format of each procedure should be agreed upon by qualified personnel. Whenever possible, the format should include the elements identified in Exhibit 5.1.
- **Writing Procedure:** The process that the author follows to develop a draft procedure in the specified format and with a level of detail commensurate with the complexity of the task documented in the procedure.
- **Reviews:** The author will submit the draft procedure for reviews as specified in QP 3.2, Technical Document Review.
- **Resolve Review Comments:** The author will resolve review comments and prepare a final procedure. If the reviewer(s) require follow-up review, the revised procedure will be resubmitted to the reviewer(s).
- **Obtain Approval:** Once approval is obtained as specified in QP 3.1, Document Control, the author will submit the procedure to the issuer.
- **Issue the Procedure:** The issuer, in consultation with the QA Officer, will determine the necessary distribution list, and distribute the procedure accordingly.
- **Periodically Review the Procedure:** The appropriate manager will determine if the procedure should be periodically reviewed for possible revisions. Revisions may be necessary to incorporate experience gained in performing the activity, to clarify or improve the procedure, incorporate new technologies, or incorporate new regulatory requirements.
- **Revise Procedures:** The appropriate manager will arrange to have procedures revised if necessary. Revisions will be performed in accordance with QP 3.1, Document Control.

5.1.8 Records

The issuer of quality procedures is responsible for maintaining the following:

- A copy of the original procedure and subsequent revisions.
- Review documentation for the original procedure and subsequent revisions.
- Distribution lists.

5.1.9 References

None.

5.1.10 Exhibits

The following exhibit is considered a part of the preparation of quality procedures:

- Exhibit 5.1 – Format for Preparation of Parametrix Quality Procedures.

EXHIBIT 5.1

Format for Preparation of Parametrix Quality Procedures

Prepared By: _____ Date: _____
Print Name, Title

Reviewed By: _____ Date: _____
Print Name, Title

Approved By: _____ Date: _____
Print Name, Title

X.X.1 Title

X.X.2 Purpose: State the purpose of the QP.

X.X.3 Scope: State when this QP is, and is not, applicable.

X.X.4 Related Procedures: List internal procedures associated with this QP.

X.X.5 Definitions: List the key words in separate paragraphs with the defined word underlined.

X.X.6 Responsibilities: List by functional title, followed by specific activities for which the person is directly responsible.

X.X.7 Procedure: List the required steps that must be performed to accomplish the task. Define who performs each step.

X.X.8 Records: List the records associated with this procedure that are required to be maintained.

X.X.9 References: List only those references that are specific to this QP. General references will be listed in a separate section.

X.X.10 Exhibits: List attached forms as:

Exhibit A – XXXXX form

Exhibit B – YYYYYY form, etc.

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5.2 CHANGE CONTROL

Prepared By:	_____	Date:	_____
	Linda R. J. Logan, PhD		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

5.2.1 Title

Change Control.

5.2.2 Purpose

To describe and assign responsibilities for Parametrix change control procedures.

5.2.3 Scope

This procedure applies to “real-time” changes that occur during Parametrix work, such as changes in fieldwork due to unforeseen conditions.

This procedure does not apply to design changes, planned project modifications, or controlling documents and procedures (e.g., work plan, QAPP), which are addressed under QP 3.1, Document Control.

5.2.4 Related Procedures

Procedures related to change control include:

- QP 3.1 – Document Control.

5.2.5 Definitions

Change is any unforeseen change from the approved controlling documents such as the Work Order Work Plan, QAPP, or technical SOP.

Minor Change is a change that would not adversely affect the quality of the work. Examples include using an equivalent field monitoring instrument, or substitution of an equally qualified individual to perform a procedure.

Major Change is a change that would affect the quality of the results or cause a significant change in the scope, schedule, or cost. Examples include using different sampling techniques, adding or eliminating field measurements or analytical requirements, or changing data quality objectives.

5.2.6 Responsibilities

Change control responsibilities include:

- **All Parametrix Project Staff:** All Parametrix staff who recognize the need for a change should report the need to the Work Order Manager.
- **Work Order Manager:** The Work Order Manager can determine whether the change is minor or major. If uncertain of the impact to quality, the Work Order Manager will consult with the Work Order QA Manager and, if necessary, the QA Officer. Minor changes can be approved by the Work Order Manager, who must then notify the Project/Deputy Project Manager of the change. Work Order Managers can approve major changes only after consultation with the Project/Deputy Project Manager. This consultation may need to involve other Parametrix personnel, the Client, or local regulatory agencies. For major changes, the Work Order Manager should notify the Work Order QA Manager and the QA Officer, who will determine the potential for impact to quality.

5.2.7 Procedures

Change order procedures shall include the following:

- **Need for Changes:** Changes should be considered as listed below.
 - Unforeseen conditions or circumstances mean that the controlling documents (e.g., work plans, QAPP, technical SOPs) cannot or should not be followed.
 - Work order quality could be enhanced.
 - Observations in-field may necessitate changes in the procedures dictated by the SAP. In those circumstances, field-based modifications will be documented and provided to Bonnie Lavelle, U.S. EPA's Remedial Project Manager, for approval.
- **Implementing Changes:** If unable to consult with the Work Order Manager, work order staff may implement minor changes immediately, but will report the changes to the Work Order Manager as soon as possible. Work order staff may not implement major changes until appropriate approvals are obtained.
- **Documenting Changes:** Changes shall be documented as listed below.
 - Minor Changes: Minor changes will be documented in work order logbooks or field logbooks, and by memoranda to the work order file
 - Major Changes: Major changes will be documented in work order logbooks, field logbooks, and by memoranda to the work order file. In addition, as specified above, one of the following will be used to document approval of major changes:
 - Use of a Change Request form (see Exhibit 5.2) or equivalent.
 - Use of a record of communication (memorandum, telephone conversation, or hard copy of an e-mail) to the project file (see Exhibit 5.3). This must include a description of the change, the reason for the change, and the printed name and signature of the person(s) approving the change.

5.2.8 Records

The following records, if applicable, will be maintained in the work order files:

- Client-specified change forms.
- Change Request forms.
- Memoranda documenting minor changes.
- Records of communication documenting approval of major changes.

5.2.9 References

None.

5.2.10 Exhibits

The following exhibits are considered a part of the change control procedure:

- Exhibit 5.2 – Example of a Change Request Form.
- Exhibit 5.3 – Example of a Record of Communication Form.

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EXHIBIT 5.2

Change Request Form

Contract/Work Order: _____ Date: _____

Requested By: _____

Description of Requested Change: _____

Reason for Change: _____

Expected Results or Impact: _____

Submit this form to the Work Order Manager immediately.

Required before implementation of major changes:

Approved By: _____ Date: _____

Work Order Manager

Date: _____

Title

cc: Work Order QA Manager
Parametrix QA Officer
Work Order File

EXHIBIT 5.3
Record of Communication Form

Record of Communication

8/99

☐ TELEPHONE COMMUNICATION

☐ INCOMING ☐ OUTGOING

INDIVIDUAL:

PHONE NO.:

ORGANIZATION:

PROJECT NO.:

PROJECT NAME:

DATE:

TIME:

BY:

ROUTE TO:

☐ PMX STAFF MEETING

☐ CLIENT/AGENCY CONSULTATION

MEETING LOCATION:

PARTICIPANTS:

Enter names of the persons who are to receive this document~

5.3 INSPECTION OF ITEMS

Prepared By:	_____	Date:	_____
	Linda R. J. Logan, PhD		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

5.3.1 Title

Inspection of Items.

5.3.2 Purpose

To describe and assign responsibilities for the Parametrix R-10 AES procedure for inspecting items.

5.3.3 Scope

This procedure applies to inspections performed on items affecting the quality of Parametrix work. It does not apply to receipt inspection of measurement and test equipment or technical services.

5.3.4 Related Procedures

Other procedures related to inspection of items include:

- QP 1.1 – Qualification and Training.
- QP 2.3 – Control of Nonconforming Items.

5.3.5 Definitions

Inspection is defined as an examination or measurement to verify whether an item conforms to specified requirements.

Inspectors are staff, who because of their expertise and training, are approved by the Parametrix QA Officer to perform specific inspections.

Hold point is defined as the point at which no further work, or use of an item, can proceed without successfully completing an inspection.

5.3.6 Responsibilities

Responsibilities for inspection of items include:

- **QA Officer**
 - Approving inspectors for their technical expertise and specific knowledge of the specified requirements.

- **Work Order Managers**
 - Identifying items requiring inspection.
 - Preparing a tentative inspection schedule and coordinating timing with the inspector.
 - Reviewing inspection reports.
 - Implementing follow-up action, if necessary.
- **Inspectors**
 - Preparing for the inspection by reviewing the appropriate controlling documents.
 - Conducting the inspection.
 - Identifying/tagging nonconforming items.
 - Preparing an inspection report.
 - Re-inspecting the item as requested by the Work Order Manager.

5.3.7 Procedures

Procedures for inspection of items include the following:

- **Need for Inspections:** At initiation of a work order, the Work Order Manager, in consultation with the Work Order QA Manager and work order staff, if necessary, should determine which items, if any, should be inspected to ensure their compliance and/or satisfactory performance. If appropriate, hold points will be identified.
- **Scheduling:** If necessary, the Work Order Manager will define a tentative inspection schedule based on the work order schedule. This schedule should be documented in the Work Order Work Plan, QAPP, or other planning documents.
- **Preparing:** The Work Order Manager will consult with the Work Order QA Manager to ensure the availability of a qualified inspector and to coordinate timing with the inspector. The inspector will initiate an item inspection (Exhibit 5.4) or equivalent by reviewing the appropriate controlling documents (e.g., manufacturer's equipment manual, operations manual, technical SOPs), paying particular attention to the specific sections that concern the item(s) to be inspected.
- **Inspecting:** During the inspection, the inspector will look for any discrepancies or variances from the controlling documents. If none are found, the inspector will report that the item has passed inspection on the inspection report. If any discrepancies or variances are found, they will be noted on the inspection report and tagged, if appropriate.
- **Reporting:** The inspector will complete the inspection report and submit it to the Work Order Manager and Work Order QA Manager as soon as possible.
- **Follow-Up:** If the item passes inspection, no follow-up is necessary. If the item does not pass inspection, the Work Order Manager will review the inspection report and take the appropriate corrective action. Nonconforming items will be reported in a nonconformance report in accordance with QP 2.3, Control of Nonconforming Items.

- **Re-inspection:** A re-inspection should be performed after the corrective action has been completed. If a hold point has been identified, activities awaiting a successful inspection can only be continued after completion of repairs/corrective action and re-inspection.

5.3.8 Records

The following records will be maintained in the work order files:

- Item Inspection Report.
- Supporting documentation for corrective steps, if applicable.

5.3.9 References

None.

5.3.10 Exhibits

The following exhibit is considered a part of the inspection of items procedures:

- Exhibit 5.4 – Item Inspection Report.

EXHIBIT 5.4

Parametrix Item Inspection Report

Contract/Work Order: _____ DCN: _____

Inspector: _____ Inspection Date: _____

Item Inspected: _____

Controlling Documents/Specifications/Procedures: _____

Specific Sections Applicable to Inspections: _____

Inspection Results (*pass/fail, hold point status, explanation, etc.*): _____

Comments, Recommendations, NCRs Issued: _____

Follow-up Required: _____

Contract/Work Order: _____ Date: _____

(Signature) _____ DCN: _____

Distribution: _____

Approved by: _____ Date: _____

Work Order Manager

cc: Work Order File

5.4 TESTING

Prepared By: _____ Date: _____
Linda R. J. Logan, PhD

Reviewed By: _____ Date: _____
Brad Hermanson, QA Officer

Approved By: _____ Date: _____
William Stubblefield, Project Manager

5.4.1 Title

Testing.

5.4.2 Purpose

To describe and assign responsibilities for the procedure at Parametrix for testing.

5.4.3 Scope

This procedure applies to testing items or techniques conducted as part of Parametrix work.
This procedure does not apply to examination or tests of personnel or computer software.

5.4.4 Related Procedures

Other procedures related to testing include:

- QP 2 – Procuring Measurement and Test Equipment.
- QP 5.3 – Inspection of Items.

5.4.5 Definitions

Testing is the process of subjecting an item to a set of operating procedures and conditions resulting in data that enable evaluation staff to determine whether the item meets the specified requirements.

Evaluation is the review of test data and results to determine if the item or technique meets the specified requirements.

5.4.6 Responsibilities

Responsibilities for testing shall include:

- **Work Order Manager**
 - Identifying items or techniques needing testing.
 - Deciding, in consultation with work order staff, the required testing procedures and conditions (i.e., instrumentation, test method, test parameters).
 - Selecting appropriately qualified test and evaluation staff.

- Deciding, in consultation with the evaluation staff, whether the acceptance criteria were met.
- **Testing Staff:** Responsible for performing the test and recording the data.
- **Evaluation Staff:** Responsible for reviewing the test data, determining if the acceptance criteria were met, and reporting on the evaluation. Evaluation staff may be the same as testing staff.

5.4.7 Procedures

Testing procedures include:

- **Performing the Test:** Testing staff will conduct the test according to the agreed upon testing procedures and conditions, and record the data on a testing form such as Exhibit 5.5, or equivalent. The summary of test results should note any variances and pertinent observations.
- **Evaluating the Test:** Evaluation staff will review the test data and compare the results to the acceptance criteria to determine if the item or technique is acceptable. The evaluator will report the results to the Work Order Manager using a Test and Evaluation Report.

5.4.8 Records

The following records will be maintained in the work order files:

- Testing data and results.
- Test and evaluation report, or equivalent.

5.4.9 References

None.

5.4.10 Exhibits

The following exhibit is considered a part of the testing quality procedure:

- Exhibit 5.5 – Parametrix Test and Evaluation Report.

EXHIBIT 5.5

Parametrix Test and Evaluation Report

Contract/Work Order _____ Test Date: _____

Testing Staff: _____

Item or Technique Tested: _____

Instrumentation Used: _____

Test Method or Procedure Used: _____

Test Parameters (*reference requirement*): _____

Calibration Data, if applicable: _____

Acceptable Criteria (*reference requirement*): _____

Summary of Test Results (*attach data*): _____

Approved by: _____ Date: _____

Tester's Signature

To be completed by evaluator.

Required before implementation of major changes:

Evaluator: _____

Evaluation of Results (Discuss deficiencies and corrective actions taken): _____

Is each item/technique acceptable? (Y / N):

Approved by: _____ Date: _____

Evaluator's Signature

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5.5 CONTROL OF SPECIAL PROCESSES

Prepared By: _____ Date: _____
Linda R. J. Logan, PhD

Reviewed By: _____ Date: _____
Brad Hermanson, QA Officer

Approved By: _____ Date: _____
William Stubblefield, Project Manager

5.5.1 Title

Control of Special Processes.

5.5.2 Purpose

To describe and assign responsibilities for procedures at Parametrix for controlling special processes.

5.5.3 Scope

This procedure applies to special processes performed by Parametrix for work that is not covered by the standard controlling documents.

5.5.4 Related Procedures

None.

5.5.5 Definitions

Special process is a process for which the results are highly dependent on the techniques used and/or the skill of the operator for which a specified quality cannot be readily determined through inspections or testing. Special processes should be identified in the appropriate planning documents.

Special Process Oversight Staff are staff with expertise in the techniques of the special process who do not perform the process but oversee and/or train those who do perform the process.

5.5.6 Responsibilities

Responsibilities for control of special processes include:

- **Work Order Manager**
 - Identifying any special processes for which controls are needed.
 - Ensuring, in consultation with the special process oversight staff, that appropriate control measures are used to evaluate performance of the special process.
 - Assigning appropriate staff to perform the special process.

- Assigning, possibly in consultation with the Work Order QA Manager, oversight staff to evaluate performance of the special process.
- **Special Process Oversight Staff**
 - Evaluating the performance of the special process.
 - Overseeing and/or training staff to perform the special process.
 - Documenting or reviewing the evaluation on a Process Control Evaluation Checklist (Exhibit 5.6) or equivalent.

5.5.7 Procedures

Procedures for control of special processes include:

- **Identifying Special Processes:** The Work Order Manager should identify any special processes during preparation of the controlling documents (e.g., Work Order Work Plan and QAPP). Controls for the special processes (e.g., operating instructions, operating conditions, or drawings) should be referenced or attached to the controlling documents.
- **Evaluating Special Process Performance:** Staff selected by the Work Order Manager should perform the special process according to the specified controls, with oversight by the special process oversight staff.

Oversight staff will:

- Observe performance of the special process.
- Immediately notify the operator of any deviations that could affect quality.
- Determine if the special process was performed correctly.
- Complete a Process Control Evaluation Checklist (Exhibit 5.6), or equivalent.

5.5.8 Records

The Process Control Evaluation Checklist, or equivalent, will be kept in the Work Order project files.

5.5.9 References

None.

5.5.10 Exhibits

The following exhibit is considered a part of the control of special processes quality procedure:

- Exhibit 5.6 – Process Control Evaluation Checklist.

EXHIBIT 5.6

Process Control Evaluation Checklist

Work Order/Title: _____ Date: _____

Name of Process: _____

What controls are available? (check as applicable; reference or attach document):

____ Codes/Standards _____
____ Instructions _____
____ Procedure _____
____ Checklist _____
____ Work Plan/QAPP _____
____ Other _____

Were the following requirements satisfied as applicable? (Y /N /NA)

Comments: _____

____ Qualified Staff? _____
____ Specified Process Parameters? _____
____ Necessary Environmental Conditions? _____
____ Procedure Followed? _____
____ Specified Codes/Standards? _____
____ Specified Equipment Requirements? _____
____ Calibration? _____
____ Maintenance? _____
____ Records Maintenance Requirements? _____

Comments: _____

Evaluated By: _____

Print Name

Signature

Date

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6. INDEPENDENT ASSESSMENTS

6.1 MANAGEMENT ASSESSMENT OF THE QA PROGRAM

Prepared By: _____ Date: _____
Suzanne C. Robinson

Reviewed By: _____ Date: _____
Brad Hermanson, QA Officer

Approved By: _____ Date: _____
William Stubblefield, Project Manager

6.1.1 Title

Management Assessment of the QA Program.

6.1.2 Purpose

To describe the procedure for conducting independent assessments of the Parametrix QA program.

6.1.3 Scope

This procedure applies to the Parametrix QA program.

6.1.4 Related Procedures

None.

6.1.5 Definitions

None.

6.1.6 Responsibilities

Responsibilities for management assessment of the quality assurance program include:

- **Parametrix Chief Operations Officer (COO):** Responsible for identifying an independent committee (the Management Assessment Committee) to implement this procedure.

6.1.7 Procedures

Procedures for assessing the QA program include:

- **Assigning the Independent Management Assessor(s):** The COO, in conjunction with the contract QA Officer, will assign Parametrix staff to an independent management assessment committee.
- **Frequency:** Management assessments will occur at least annually, or more frequently at the discretion of the COO.

- **Management Assessment Conduct:** The assessment will address each element listed below.
 - Adequacy of the organizational structure and staffing of the QA program to discharge its duties.
 - Adequacy of the QA program to meet the general and specific QA management requirements of the contract.
 - Established reporting mechanisms in place to convey assessment findings to management.
- **Management Assessment Documentation:** The management assessment team will provide a written report to the COO and QA Officer, with a copy to the contract Project Manager. The report will address each of the items noted under Management Assessment Conduct and will include any positive findings, identified deficiencies, and corrective actions.
- **Assessment Responsiveness Summary:** The COO, in conjunction with the QA Officer, will review the management assessment report and identify/document any impediments or unintended consequences associated with implementing report recommendations and/or corrective actions. The COO will identify the staff responsible for overseeing the implementation of any recommended actions.

6.1.8 Records

The management assessment report and the assessment responsiveness summary will be retained in the QA program files by the QA Officer.

6.1.9 References

Other references regarding QA programs include:

- ANSI/ASQC E4-1994. Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.
- EPA QA/R-2, U.S. Environmental Protection Agency. 2001. EPA Requirements for Quality Management Plans (QMPs). Office of Environmental Information, Washington, D.C. EPA/240/B 01/002.

6.1.10 Exhibits

None.

6.2 AUDITS

Prepared By:	_____	Date:	_____
	Suzanne C. Robinson		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

6.2.1 Title

Quality Assurance Audits.

6.2.2 Purpose

To describe the system for conducting independent QA program audits.

6.2.3 Scope

This procedure applies to QA audits of the technical work conducted by Parametrix and its subcontractors.

6.2.4 Related Procedures

Other procedures related to audits include:

- QP 8.1 – Corrective Action.

6.2.5 Definitions

A Work Order is a negotiated document as defined by the Client.

Audit is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements, and whether these arrangements are implemented effectively and in a manner suitable to achieving project objectives. There are three types of audits addressed in this procedure: field, laboratory, and office.

A Field Audit is an independent on-site review during the conduct of field activities to assess compliance with the methods, procedures, and quality measures established in the field planning documents.

A Laboratory Audit is an independent on-site review at the laboratory facility(s) to assess compliance with the analytical methods, procedures, and quality measures established in the laboratory's quality assurance plan and in the subcontract statement of work.

An Office Audit is an independent evaluation of the procedures and methods established in the QAPP and/or Work Order Work Plan. The office audit is typically conducted at the location where the project files are stored and maintained.

6.2.6 Responsibilities

Audit responsibilities include:

- **QA Officer:** The QA Officer reports directly to the Parametrix COO. Responsibilities include identifying Work Order QA Manager(s), establishing the audit program, approving QA auditors, approving and issuing QA audit reports, and determining audit requirements.
- **Work Order QA Manager:** The Work Order QA Manager is assigned by and reports directly to the QA Officer. Responsibilities of the Work Order QA Manager include consulting with the Work Order Manager to determine work-order-specific audit requirements, assisting the QA Officer in selection of auditors from the QA staff, and assisting (as needed) in the preparation of the audit report and follow-up corrective actions.
- **QA Staff:** QA Staff members perform audits required by the QA Officer and Work Order QA Manager, and report and follow up on audit results.
- **Auditors:** Auditors are QA staff members with direct responsibility for scheduling, planning, conducting, documenting, and reporting audits. Auditors are responsible for immediately notifying the Work Order Manager, Project/Deputy Project Manager, and QA Officer of quality deficiencies that may adversely affect the quality of project data.

6.2.7 Procedures

Audit procedures include:

- **Auditor Qualifications:** Personnel conducting audits will possess the appropriate technical and/or management skills to perform the assigned audit based on work-order-specific requirements.
- **Auditor Selection:** The QA Officer, in consultation with the Work Order Manager, will assign the auditor(s) responsible for conducting and/or coordinating the audits for each work order.
- **Selection and Timing of Work Order Audits:** The QA Officer will identify the projects to be audited, usually at the start of a project. Projects subject to audits will be identified in writing on a routine basis.
- **Audit Preparation:** Audit preparation shall be completed as described below.
 - **Audit Plan:** The assigned auditor will prepare an audit plan that includes the following: project elements to be audited, the type and scope of the audit, any specific requirements or documents, the person(s) to be notified of the audit, the name of the auditor(s), and the schedule. The audit plan will be reviewed and approved by the QA Officer or Work Order QA Manager prior to distribution.
 - **Notification:** For “announced” audits, the auditor will verbally inform the Work Order Manager a minimum of two weeks before the date of a planned audit. A copy of the approved audit plan will be provided to the Work Order Manager at the time of notification. For “unannounced audits” directed by the Client, oversight regulatory agency, or Parametrix, no advance notification will be provided.
 - **Audit Forms:** The auditor will develop or tailor an existing audit checklist to address the work-order-specific requirements of each audit.

- **Audit Conduct and Documentation:** The auditor will examine activities (according to the type of audit performed) to determine if the activities are in compliance with the QAPP and associated SOPs, work order work plan, and/or other governing documents. The auditor will document the audit and maintain a list of all personnel contacted during the audit. Key findings of the audit, particularly any identified deficiencies, will be verbally discussed with the Work Order Manager immediately following conclusion of the audit so that corrective action(s) can be rapidly initiated.
- **Audit Report:** The auditor will prepare an audit report within 15 working days from the time of audit completion for review and approval by the QA Officer and Work Order QA Manager.

The audit report will include:

- Date and location of the audit.
- Description of the audit scope.
- Name of the auditor(s).
- Name of personnel contacted during the audit.
- Audit Findings: Positive results or clear deviations from documented requirements, required corrective action(s), and a statement of audit completion.
- Corrective Action Request (if applicable).
- A copy of the completed audit plan.

An audit will be considered complete if no deficiencies are identified, all identified deficiencies are resolved, or any unresolved deficiencies are addressed in one or more Correction Action Requests to the Work Order Manager. Once approved by the QA Officer and Work Order QA Manager, the auditor, Work Order QA Manager, and QA Officer will each sign the report and issue it within 30 business days from the time of audit completion.

- **Audit Report Recipients:** The Project/Deputy Project Manager, Work Order Managers, and QA Officer shall each receive a copy of the approved audit report. A copy of the approved audit report will also be placed in work order/contract files. The QA Officer will, on a routine basis, provide to the COO a list of the completed project audit reports.
- **Follow-up Audit Activities:** Should unresolved deficiencies remain, the auditor will issue any necessary Corrective Action Requests to the Work Order Manager to ensure that these deficiencies are resolved. QP 8.1 further addresses the specific steps for following up on Corrective Action Requests.

6.2.8 Records

All records related to the audit(s) will be kept in the work order/contract files. Audit records will include the audit plan, the completed audit checklist, approved audit report, and completed Corrective Action Requests (if applicable).

6.2.9 References

Additional references regarding audits include:

- ANSI/ASQC E4-1994. Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.
- EPA QA/R-2, U.S. Environmental Protection Agency. 2001. EPA Requirements for QMPs. Office of Environmental Information, Washington, D.C. EPA/240/B 01/002.

6.2.10 Exhibits

Exhibits relating to this audit quality procedure include:

- Exhibit 6.1 – Contract Quality Management Procedures: Audits.

EXHIBIT 6.1

Contract Quality Management Procedures: Audits

Audit Title: _____ Date: _____

(If Applicable)

Audit Type (Office, Laboratory, Field): _____

Project/Activity: _____

Audit Scope: _____

Requirements/Applicable Document (list all relevant documents reviewed): _____

Specific Activities to be Audited: _____

Persons/Affiliations to be Notified: _____

Auditor(s): _____

Audit Schedule (Initiation, Completion): _____

Prepared By: _____

Reviewed By: _____

Work Order QA Manager

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6.3 QUALITY ASSURANCE SURVEILLANCES

Prepared By: _____ Date: _____
Suzanne C. Robinson

Reviewed By: _____ Date: _____
Brad Hermanson, QA Officer

Approved By: _____ Date: _____
William Stubblefield, Project Manager

6.3.1 Title

Quality Assurance Surveillances.

6.3.2 Purpose

To describe the system for the conduct of QA surveillances at Parametrix.

6.3.3 Scope

This procedure applies to surveillances of technical work conducted by Parametrix and its subcontractors.

6.3.4 Related Procedures

Procedures related to quality assurance surveillances include:

- QP 6.2 – Audits.
- QP 8.1 – Corrective Actions.

6.3.5 Definitions

A Work Order is a negotiated document defined contractually.

Work Order Staff are defined as technical and administrative staff engaged in the daily activities required to fulfill work order objectives.

Surveillance is ongoing and/or frequent monitoring and verification of the implementation of QA and QC procedures by work order staff. Surveillance is typically narrower in scope than an audit, with a less formal report. There are three types of surveillances addressed in this procedure: field, laboratory, and office.

Field Surveillance is an on-site review during the conduct of field activities to assess work order staff compliance with the methods, procedures, and quality measures established in the field planning documents.

Laboratory Surveillance is an on-site review at the laboratory facility(s) to assess compliance with the analytical methods, procedures, and quality measures established in the laboratory's quality assurance plan and in the subcontract documents.

Office Surveillance is an evaluation of the procedures and methods established in the Work Order Work Plan or QAPP. Office surveillance is typically conducted at the location where the work order files are stored and maintained.

6.3.6 Responsibilities

Responsibilities for quality assurance surveillance include:

- **QA Officer: Reports directly to the Parametrix COO.** The responsibilities of the QA Officer include identifying a Work Order QA Manager, establishing a work-order-specific surveillance program, qualifying QA Staff to perform surveillances, approving and issuing surveillance reports, and determining surveillance requirements.
- **Work Order QA Manager:** The Work Order QA Manager is assigned by and reports directly to the QA Officer. Responsibilities of the Work Order QA Manager include establishing work-order-specific surveillance requirements, assisting the QA Officer in selection of surveillants from the QA staff, and reviewing and approving surveillance reports.
- **QA Staff:** Responsibilities of the QA staff include arranging and/or performing surveillances required by the QA Officer and Work Order QA Manager, preparing surveillance reports, and following up on identified corrective actions.
- **Surveillant:** A QA staff member with direct responsibility for scheduling, planning, conducting, documenting, and reporting project surveillance activities. Surveillants are responsible for immediately notifying the Work Order QA Manager, QA Officer, Work Order Manager, and Project/Deputy Project Manager of any deficiencies that may adversely affect the quality of project data or the health and safety of project staff.

6.3.7 Procedures

Quality assurance surveillance procedures include:

- **Surveillant Identification:** The QA Officer, in consultation with the Work Order QA Manager, will identify surveillants from among the QA staff. Surveillants must possess the appropriate technical and/or management skills to perform the assigned surveillance based on work-order-specific requirements.
- **Surveillant Selection:** The QA Officer and Work Order QA Manager will select and assign a surveillant from available QA staff to conduct and/or coordinate each surveillance activity on each work order. A QA staff member may perform both surveillance and audits.
- **Selection and Timing of Surveillance Activities:** The QA Officer, in consultation with the Work Order QA Manager, will identify the work order requirements for surveillance, usually at the start of the project.
- **Surveillance Preparation:** Activities described below will be a part of the surveillance preparation.
 - **Planning:** The surveillant will review the work order files prior to initiating surveillance activities, including all pertinent background documents such as previous work order audit and surveillance reports, corrective action summaries,

and other findings (positive, negative) necessary to prepare for a surveillance activity.

- **Notification:** The surveillant will verbally notify the Work Order Manager a minimum of one week before the date of a planned surveillance activity.
- **Surveillance Checklist:** The surveillant will develop or tailor a checklist to address the work-order-specific requirements for surveillance.
- **Surveillance Conduct:** The surveillant will examine selected activities (according to the type of surveillance performed) to determine if the activities are in compliance with the QAPP, SOPs, Work Order Work Plans, and other governing documents. The surveillant will record all surveillance findings on the surveillance checklist and maintain a list of all personnel contacted during the surveillance. The key findings of the surveillance, particularly any identified deficiencies, will be verbally discussed with the Work Order Manager immediately following conclusion of the surveillance so that corrective actions can be rapidly initiated.
- **Surveillance Report:** The surveillant will prepare a brief surveillance report, within 15 working days from the time of surveillance completion, for review and approval by the QA Officer and Work Order QA Manager. The surveillance report will include:
 - Date and location of the surveillance activity.
 - Description of the surveillance activities performed.
 - Name of the surveillant.
 - Description of controlling documents.
 - Name of personnel contacted during the audit.
 - Surveillance findings (proficiencies and deficiencies from documented requirements).
 - A summary of corrective action(s) taken or required.

An example format for a surveillance report is provided in Exhibit 6.2. The report may be handwritten or typed. Once approved by the QA Officer and Work Order QA Manager, the surveillant and/or QA Officer (or Work Order QA Manager) will sign the report and issue it within 30 business days from the time of surveillance completion.

- **Surveillance Report Recipients:** The Project/Deputy Project Manager, Work Order Manager, Work Order QA Manager, and QA Officer shall each receive a copy of the approved surveillance report. The QA Officer will provide a list of the completed project surveillance reports to the COO.
- **Surveillance Follow-Up:** Should unresolved deficiencies remain, the surveillant will issue any necessary Corrective Action Requests to the Work Order Manager to ensure that deficiencies are resolved. The Work Order QA Manager will issue a notification noting completion of any corrective actions. QP 8.1 further addresses the specific steps for following up on Corrective Action Requests.

6.3.8 Records

All records related to surveillance(s) will be kept in the work order/contract files. Surveillance records will include the completed surveillance checklist, approved surveillance report, and completed corrective action requests, if applicable.

6.3.9 References

Other references regarding quality assurance surveillance include:

- ANSI/ASQC E4-1994. Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.
- EPA QA/R-2, U.S. Environmental Protection Agency. 2001. EPA Requirements for QMPs. Office of Environmental Information, Washington, D.C. EPA/240/B 01/002.

6.3.10 Exhibits

The following exhibit is considered a part of this quality procedure:

- Exhibit 6.2 – Contract Quality Management Procedures: Surveillance Report.

EXHIBIT 6.2

Contract Quality Management Procedures: Surveillance Report

Document Control No.: _____ Date: _____

Contract/Project No./Title (if applicable): _____

Date Conducted: _____ Surveillance Type/Location: _____

Name/Title (surveillant): _____

Project Personnel Contacted/Reason: _____

Controlling Documents/Procedures Applicable to Surveillance (List all; indicate Specific Sections):

Activities /Documentation Reviewed (list each):

Proficiencies:

Deficiencies:

EXHIBIT 6.2

Contract Quality Management Procedures: Surveillance Report (continued)

Further Corrective action required for uncorrected deficiencies? (Y / N) If YES, attach Corrective Action Request (CAR).

The Corrective Action Designee is responsible for taking appropriate corrective action, briefly describing it on the CAR, and returning the completed form, along with evidence of corrective action taken by the Work Order QA Manager by the date indicated.

Work Order QA Manager (name): _____

Corrective action taken to address each deficiency. Describe objective evidence observed or reviewed that demonstrates corrective action was implemented for each deficiency:

Surveillance Report Prepared By: _____

Surveillance Report Approved By: _____

QA Officer or Work Order QA Manager

7. PROJECT SELF-ASSESSMENTS

7.1 WORK ORDER SELF-ASSESSMENTS

Prepared By: _____ Date: _____
Suzanne C. Robinson

Reviewed By: _____ Date: _____
Brad Hermanson, QA Officer

Approved By: _____ Date: _____
William Stubblefield, Project Manager

7.1.1 Title

Work Order Self-Assessments.

7.1.2 Purpose

To describe the system and responsibilities for conducting self-assessments by Parametrix personnel.

7.1.3 Scope

This procedure applies to technical work conducted by Parametrix staff. Self-assessments may be conducted with the intent to potentially lessen the office audit or office surveillance requirements on a project.

7.1.4 Related Procedures

Procedure related to work order self-assessments includes:

- QP 8 – Corrective Action.

7.1.5 Definitions

Self-assessment represents an assessment of work conducted by individuals or groups directly responsible for overseeing and/or performing the work on a project.

A Work Order is a negotiated document defined contractually.

7.1.6 Responsibilities

Work order self-assessment responsibilities include:

- **Work Order Manager:** In consultation with the Work Order QA Manager, the Work Order Manager will:
 - Identify activities for self-assessment.
 - Identify personnel to conduct self-assessments (assessors).
 - Review, approve, and file self-assessment reports (optional).
 - Implement corrective actions as necessary.

- **Work Order QA Manager:** The Work Order QA Manager will provide oversight and assistance to the self-assessment. Specifically he/she will:
 - Develop standard checklists.
 - Concur with planned self-assessments.
 - Track the performance of required self-assessments.
- **Assessor:** The assessor is the person conducting the self-assessment. The assessor is responsible for:
 - Reviewing work order requirements and preparing or modifying a checklist as needed.
 - Conducting the self-assessment using a checklist.
 - Promptly notifying the Work Order Manager upon identifying an adverse condition that may affect the quality of data or project results.
 - Preparing the self-assessment report and submitting it to the Work Order Manager.

7.1.7 Procedures

Procedures for work order self-assessments include:

- **Self-Assessment Activities:** The Work Order Manager will select the specific activities within a work order that are subject to self-assessment.
- **Assessor Selection:** The Work Order Manager will select assessors based on their experience and work-order-specific knowledge of the activity scheduled for self-assessment. The assessor will have sufficient authority, access to managers, and freedom to identify and document problems.
- **Self-Assessment Preparation:** The activities described below are a part of self-assessment preparation.
 - Planning: The assessor will review governing documents to determine the applicable requirements.
 - Checklist: The assessor will prepare an activity-specific checklist or tailor an existing (standard) checklist that includes the applicable technical requirements.
- **Performance:** Selected activities will be examined by the assessor to determine if the activities are in conformance with the requirements of the QAPP, Work Order Work Plan, SOPs, and other governing documents. All personnel contacted during the self-assessment should be listed on the checklist.
- **Report Options:** The assessor will prepare a report documenting the findings of the self-assessment. The Work Order Manager should specify any specific report requirements. Because self-assessments are intended to provide rapid feedback to the work order staff, simplified reports that can be prepared and issued quickly are encouraged.

Report options include:

- The completed, signed, and dated checklist.
- The completed, signed, and dated checklist with a summary of the assessment.

- A report similar to the surveillance report form shown in QP 6.3, Exhibit 6.2.

The self-assessment report will be signed by the assessor and submitted to the Work Order Manager to review, approve, and file. Copies of the report will be sent to the assessed group, the Work Order QA Manager, the QA Officer, the Work Order Manager, and the Project/Deputy Project Manager.

- **Corrective Action:** The group assessed will correct any deficiencies identified by the assessment. Rapid corrective action is encouraged to benefit the project work. The deficiency and the action taken to correct it should be documented in a memorandum or other written form as directed by the Work Order Manager.

If rapid corrective action is not possible, an Improvement Plan (Exhibit 7.1), or equivalent, should be initiated and attached to the self-assessment report. The Improvement Plan should identify the situation needing improvement and should provide a plan of action with a scheduled completion date. Upon completion of the actions, the Work Order Manager should sign off on the Improvement Plan.

7.1.8 Records

The self-assessment reports and completed Improvement Plans (if any) will be maintained in the work order files.

7.1.9 References

References related to work order self-assessments include:

- ANSI/ASQC E4-1994. Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.
- EPA QA/R-2, U.S. Environmental Protection Agency. 2001. EPA Requirements for QMPs. Office of Environmental Information, Washington, D.C. EPA/240/B 01/002.

7.1.10 Exhibits

Exhibits included as a part of the work order self-assessment include the following:

- Exhibit 7.1 – Contract Quality Management Procedures: Improvement Plan.

EXHIBIT 7.1

Project No./Title: _____	
Client/Contract: _____	
Work Order Manager: _____	Work Order QA Manager: _____
Situation (attach additional pages as required):	
Situation Identified By: _____	Date: _____
Plan of Action (attach additional pages as required):	
Responsible for Action: _____	
Schedule Completion Date: _____	
Actual Completion Date: _____	
Work Order Manager Signature: _____	Date: _____

8. RESPONSE TO ASSESSMENTS

8.1 CORRECTIVE ACTION

Prepared By:	_____	Date:	_____
	Suzanne C. Robinson		
Reviewed By:	_____	Date:	_____
	Brad Hermanson, QA Officer		
Approved By:	_____	Date:	_____
	William Stubblefield, Project Manager		

8.1.1 Title

Corrective Action.

8.1.2 Purpose

To describe the Parametrix system for conducting corrective actions.

8.1.3 Scope

This procedure applies to corrective actions required for any Parametrix work.

8.1.4 Related Procedures

Other procedures related to corrective action include:

- QP 6.1 – Management Assessment of the Quality Assurance Program.
- QP 6.2 – Audits.
- QP 6.3 – Surveillance.
- QP 7.1 – Project Self-Assessments.

8.1.5 Definitions

A Deficiency or other quality “problem” represents a condition or situation that is detrimental or potentially detrimental to quality. Examples include deviations from a contract-wide QMP, Work Order Work Plan, or technical standard operating procedure or from other program or project requirements.

A Work Order is a negotiated document defined contractually.

A Significant Condition Adverse to Quality is any condition that, were it to remain uncorrected, could have a serious adverse impact on the validity or credibility of project conclusions.

Programmatic Cause is the most basic reason for a significant condition adverse to quality, which, if corrected or precluded, would prevent that condition from recurring.

8.1.6 Responsibilities

Corrective action responsibilities include:

- **All Contract Personnel:** Responsible for identifying and reporting quality problems and correcting problems within their authority as soon as possible.
- **Corrective Action Designee:** Person identified on a Corrective Action Request with responsibility for ensuring that the corrective action(s) is implemented to address quality problems and for providing evidence that the corrective action has been completed.
- **Work Order QA Manager:** Responsible for tracking, reviewing, accepting, and verifying corrective actions documented on Corrective Action Requests. The Work Order QA Manager is responsible for identifying significant conditions adverse to quality and for reporting these conditions to the Work Order Manager, Project/Deputy Project Manager, and QA Officer. The Work Order Manager will ensure that all corrective actions are entered into the Corrective Action Log maintained in the master project files.

8.1.7 Procedures

Corrective action procedures include:

- **Identifying Quality Problems or Deficiencies:** All personnel shall identify problems or deficiencies encountered during routine work order activities. When in doubt, personnel should discuss any potential quality concerns with the Work Order QA Manager to determine whether the issue truly represents a potential quality problem or deficiency. The QA staff is responsible for identifying quality problems or deficiencies during audit or surveillance activities.
- **Rapid Corrective Action Documentation:** During routine work order work, rapid corrective action is encouraged at all times because this benefits the work in a timely manner. Where rapid corrective action occurs for minor problems, the date, problem encountered, and rapid corrective action will be documented in a work order notebook (or equivalent) consistent with normal operating procedures.

During an audit or surveillance, rapid corrective actions approved by the Work Order Manager (or other on-site responsible person) are also encouraged. In these instances, the Work Order Manager or other responsible person authorizing the rapid corrective action will notify the auditor within 5 to 10 days from the audit date when the deficiencies were corrected. The deficiency and the corrective action will be documented in the audit or surveillance report.
- **Formalized Corrective Action Documentation:** Problems or deficiencies not rapidly corrected should be identified by the person identifying the problem on a formal Corrective Action Request form and provided to the Work Order QA Manager for investigation and resolution (see Exhibit 8.1 for an example corrective action request). The corrective action request identifies the deficiency and date of occurrence, the significant conditions adverse to quality (if any), the corrective action designee (person responsible for corrective action), and the date for corrective action to be implemented. Documentation includes:

- Significant Conditions Adverse to Quality: In the infrequent instance where such a condition may exist, the Work Order QA Manager, in consultation with the QA Officer and affected managers (Project, Work Order), will identify whether the problem or deficiency truly represents a significant condition adverse to quality. If so deemed, the QA Officer will report the condition to the COO in writing and will include the associated Corrective Action Request form. The QA Officer, with the affected managers, will determine the appropriate corrective action and ensure that it is completed.
- Corrective Action Designee: The Work Order QA Manager will identify the person responsible (corrective action designee) for implementing the corrective action (typically the Work Order Manager), set a date on which the response is due, and distribute the Corrective Action Request. If a Corrective Action Request is initiated during an audit or surveillance, the Corrective Action Request will become a part of the audit or surveillance report.
- Implementing the Corrective Action: The corrective action designee should identify the cause of the problem, as well as the steps taken to correct the problem, on the Corrective Action Request form (see the Corrective Action Response section on the form). Should it be infeasible to complete the corrective action response with supporting evidence by the date the corrective action request form is due to the corrective action designee, document the corrective action response (problem, date corrective action to be complete, and steps taken to implement corrective action) in a separate corrective action plan.
- **Accepting and Verifying Formal Corrective Action**: Formal corrective action shall be accepted and verified as listed below:
 - Reviewing Corrective Action: The Work Order QA Manager will review the corrective action response (on the corrective action request form) to determine the adequacy of the corrective action. If the corrective action appears appropriate, the Work Order QA Manager will examine the supporting evidence that the corrective action has been completed.
 - Verifying Corrective Action: If evidence that the corrective action completion has been completed is acceptable, the Work Order QA Manager will sign and date the form on the "Corrective Action Verified By" line of the form. If evidence of corrective action completion is obtained through audit, surveillance, or follow-up review, the individual conducting the follow-up will sign and date the form on the "Corrective Action Verified By" line of the form.
 - Accepting Corrective Action: After verifying that appropriate corrective action has been taken, the Work Order QA Manager will sign on the "Corrective Action Accepted" line of the form and distribute the form to the original recipients.
 - Accepting Corrective Action Plans: In those instances where a corrective action plan is prepared, the Work Order QA Manager will review the corrective action plan to determine the acceptability of the planned corrective action and its stated time frame. If acceptable, the Work Order QA Manager will sign on the "Corrective Action Plan Accepted" line of the form and notify the original recipients of the Corrective Action Request that the plan is acceptable. When evidence of corrective action taken is available, the corrective action designee will forward this evidence to the Work Order QA Manager for verification.

- **Unacceptable Corrective Action Response:** Though it is hoped that these procedures will seldom be used, should the corrective action or evidence of completion be deemed unacceptable, or should no action be taken by the due date, the Work Order QA Manager will issue a new Corrective Action Request with a copy of the original Corrective Action Request attached. The reissued Corrective Action Request will list both the corrective action designee and that person's supervisor as responsible for action. A new response date, not to exceed 30 days from the date of reissue, will be identified for a corrective action response.

In those instances where a reissue of the corrective action request still does not result in a timely or acceptable response, the Work Order QA Manager will notify the QA Officer in writing. The QA Officer will work with the corrective action designee to encourage an expedited response.

8.1.8 Records

The following records will be maintained in the master project files:

- Completed Corrective Action Request forms.
- Supporting documentation (if applicable).
- Corrective Action Plans (if applicable).
- Corrective Action Log.

8.1.9 References

References related to corrective action include:

- ANSI/ASQC E4-1994. Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.
- EPA QA/R-2, U.S. Environmental Protection Agency. 2001. EPA Requirements for QMPs. Office of Environmental Information, Washington, D.C. EPA/240/B 01/002.

8.1.10 Exhibits

The following exhibit is included as a part of the corrective action quality procedure.

- Exhibit 8.1 – Corrective Action Request Form.

EXHIBIT 8.1
Parametrix Corrective Action Request

Project: _____

Contract/Project No.: _____ Work Order Manager: _____

Description of problem and date identified: _____

Project Personnel Contacted/Reason: _____

Requested by: _____ Date: _____

Submit this form to the Work Order Manager promptly.

Significant Condition Adverse to Quality? (Y / N)

Corrective Action Designee: _____ Response Date: _____

Submit completed response to: _____

Corrective Action Response

[To be completed by the corrective action designee. Attach additional pages as required. Include evidence that corrective action has been implemented.]

State cause of problem (if known or suspected): _____

Corrective Action(s) Taken to Correct Problem and Prevent Recurrence: _____

Corrective Action Designee Signature: _____ Date: _____

Corrective Action Designee Accepted: _____ Date: _____

Corrective Action Verified By: _____ Date: _____

Corrective Action Accepted: _____ Date: _____

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9. CONTINUOUS IMPROVEMENT

9.1 CONTINUOUS IMPROVEMENT

Prepared By: _____ Date: _____
Linda R. J. Logan, PhD

Reviewed By: _____ Date: _____
Brad Hermanson, QA Officer

Approved By: _____ Date: _____
William Stubblefield, Project Manager

9.1.1 Title

Continuous Improvement.

9.1.2 Purpose

To describe the procedure for continuous quality improvement of Parametrix work.

9.1.3 Scope

This procedure applies to all activities performed by the Parametrix staff.

9.1.4 Related Procedures

Procedures related to continuous improvement include:

- QP 6.2 – Audits.
- QP 6.3 – Surveillance.
- QP 7.1 – Self-Assessments.
- QP 8.1 – Corrective Action.

9.1.5 Definitions

Improvement is a change that adds value to a project, such as upgrading the quality of a work product, increasing efficiency, reducing costs, correcting a deficiency, or providing enhanced value to the Client.

9.1.6 Responsibilities

All Parametrix and Parametrix subcontractor staff are responsible for identifying opportunities for improvement and reporting these opportunities to their immediate supervisor or manager. Responsible parties include:

- **Work Order Managers**
 - Encouraging staff to keep continuous improvement in mind.
 - Encouraging improvement by promoting teamwork.

- Using planning meetings (i.e., work order kick-off, field planning, health and safety) to discuss opportunities for improvement.
- Evaluating suggested improvements.
- Implementing improvements as appropriate.
- **Project Manager**
 - Evaluating and responding to suggested improvements.
 - Implementing improvements as appropriate.
- **QA Officer:** Attending field-planning meetings to provide input on the quality requirements, either by attending the meeting or contributing to the meeting agenda.

9.1.7 Procedures

Procedures for addressing continuous improvement include:

- **Improvement Opportunities:** All staff should be alert to seeking improvements in the work they perform. To assist this, the elements listed below should be implemented as appropriate:
 - Kick-off Meetings: Should be held by the Work Order Manager at the initiation of a work order. The meeting should be interactive and participatory, emphasizing an understanding of the work order scope, schedule, and budget; critical path items; and opportunities for continuous improvement. Minutes of the meeting and attendance will be maintained in the work order project file.
 - Field Planning Meetings: Interactive sessions attended by field teams before fieldwork begins to ensure that staff understand the scope, schedule, and budget of the fieldwork; discuss any work-order-specific health and safety issues; to solicit suggestions for improvement; and to prepare and/or review the readiness checklist, if appropriate. The Work Order QA Manager should provide input on the quality requirements either by attending the meeting or contributing to the meeting agenda. Meeting minutes and attendance will be maintained in the work order files.
 - Self Assessments: Continuous evaluations staff should make for improving their own activities on a daily basis. These assessments can be conducted in a manner similar to QP 7.1, Project Self-Assessments. Self-assessments are encouraged because they promote ownership responsibility and can potentially lessen the frequency for audits and surveillance.
 - Management Assessment, Audits, and Surveillances: These activities are conducted to identify improvement opportunities in accordance with QP 6.1, Management Assessment of the QA Program; QP 6.2, Audits; and QP 6.3, Surveillances. Deficiencies are reported to the responsible managers.
- **Evaluating Improvement Suggestions:** Improvement suggestions should be evaluated to determine the benefits, impacts, unintended consequences, and viability of a suggested improvement. Improvement suggestions identified during kick-off meetings and/or field-planning meetings are evaluated by the team, which may defer to other technical staff or management staff.

Improvements suggested are evaluated by Work Order Managers, the Project/Deputy Project Manager, and other technical or management staff, as appropriate.

- **Implementing Improvements:** Some improvement suggestions can be implemented immediately based on an evaluation by the Work Order Manager; others may need further evaluation or approval from the Project/Deputy Project Manager.

Improvements required as a result of a Corrective Action Request will be implemented according to QP 8.1, Corrective Action.

9.1.8 Records

As appropriate, the following records will be maintained in the work order project files:

- Minutes and attendance sheets from kick-off meetings and field planning meetings.
- Completed readiness checklists.

9.1.9 References

None.

9.1.10 Exhibits

None.

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APPENDIX A

Quality Assurance Project Plan for Remedium Work Orders

Appendix A - Draft Quality Assurance Project Plan for Remedium Work Orders Revision No. 0

Prepared for

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CITATION

Parametrix Environmental Research Lab. 2008. Appendix A - Draft Quality Assurance Project Plan for Remedium Work Orders
Revision No. 0. Prepared by Parametrix, Albany, Oregon. August 25, 2008.

APPROVALS

Appendix A Draft Quality Assurance Project Plan for Remedium Work Orders

Prepared for
Remedium Group, Inc.

Parametrix, Brad Hermanson, Quality Assurance Officer

Date

Parametrix, William Stubblefield, Project Manager

Date

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DISTRIBUTION LIST

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Robert Marriam	Client Project Manager	Remedium
TBD	Work Order Manager(s)	Parametrix
Contract File		Parametrix

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TABLE OF CONTENTS

1. INTRODUCTION	A1-1
2. QUALITY ASSURANCE ORGANIZATION AND RESPONSIBILITIES	A2-1
2.1 ORGANIZATION AND MANAGEMENT	A2-1
2.1.1 Parametrix Organization	A2-1
2.1.2 Program and Work Order Management Staff	A2-2
2.1.3 Subcontractor QA Requirements	A2-2
2.2 QUALITY MANAGEMENT RESPONSIBILITIES/AUTHORITIES	A2-3
2.2.1 Parametrix QA Officer	A2-3
2.2.2 Parametrix Contract Management Staff	A2-3
2.2.3 Work Order QA Managers	A2-4
2.2.4 Subcontractor QA Managers	A2-4
2.2.5 Analytical Services Coordinator	A2-5
2.2.6 Field Operations Coordinator	A2-5
2.2.7 All Employees	A2-6
3. PROBLEM DEFINITION/BACKGROUND	A3-1
4. WORK ORDER DESCRIPTION	A4-1
5. QUALITY OBJECTIVES AND CRITERIA	A5-1
6. PERSONNEL TRAINING/CERTIFICATION	A6-1
6.1 TRAINING AND QUALITY	A6-1
6.2 TRAINING NEEDS ASSESSMENT AND IMPLEMENTATION	A6-1
6.3 TRAINING DOCUMENTATION	A6-2
7. DOCUMENTS AND RECORDS	A7-1
7.1 DOCUMENTS	A7-1
7.2 RECORDS	A7-1
8. SAMPLING PROCESS DESIGN	A8-1
8.1 GENERAL SAMPLING PROCESS DESIGN	A8-1
8.2 SAMPLING STRATEGIES	A8-1
8.3 DETERMINATION OF SAMPLING CRITERIA	A8-2
9. SAMPLING METHODS REQUIREMENTS	A9-1
10. SAMPLE HANDLING AND CUSTODY REQUIREMENTS	A10-1
10.1 SAMPLE HANDLING AND DOCUMENTATION	A10-1
11. ANALYTICAL METHODS REQUIREMENTS	A11-1
12. QUALITY CONTROL REQUIREMENTS	A12-1
12.1 FIELD PLANNING MEETINGS	A12-1

TABLE OF CONTENTS (CONTINUED)

12.2 INTERNAL QC CHECKS AND FREQUENCY FOR SAMPLE COLLECTION	A12-1
12.3 INTERNAL QC CHECKS AND FREQUENCY FOR LABORATORY ANALYSIS.....	A12-3
13. INSTRUMENT AND EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE REQUIREMENTS	A13-1
14. INSTRUMENT CALIBRATION AND FREQUENCY	A14-1
14.1 FIELD EQUIPMENT	A14-1
14.2 LABORATORY EQUIPMENT	A14-2
15. INSPECTION/ACCEPTANCE REQUIREMENTS FOR SUPPLIES AND CONSUMABLES.....	A15-1
16. NON-DIRECT MEASUREMENTS	A16-1
17. DATA MANAGEMENT	A17-1
17.1 MANAGEMENT OF FIELD DATA.....	A17-1
17.2 MANAGEMENT OF LABORATORY DATA.....	A17-1
17.3 DATA STORAGE, RETRIEVAL, AND ANALYSIS OF ELECTRONIC MEDIA	A17-2
18. ASSESSMENTS AND RESPONSES	A18-1
18.1 MANAGEMENT ASSESSMENTS	A18-1
18.1.1 Management Self-Assessment.....	A18-1
18.1.2 Independent Management Assessments	A18-2
18.2 TECHNICAL ASSESSMENTS	A18-2
18.2.1 Technical Self-Assessments	A18-2
18.2.2 Technical Independent Assessments	A18-3
18.3 FREQUENCY OF INDEPENDENT ASSESSMENTS	A18-4
18.4 RESPONSE TO ASSESSMENTS.....	A18-5
18.4.1 Purpose of Assessments.....	A18-5
18.4.2 Responses to Different Types of Assessments	A18-5
18.5 CORRECTIVE ACTION SYSTEM.....	A18-7
18.5.1 Organizational Corrective Action.....	A18-7
19. DATA REVIEW, VALIDATION, AND VERIFICATION REQUIREMENTS ...	A19-1
20. VALIDATION AND VERIFICATION METHODS.....	A20-1
20.1 DATA VALIDATION REQUIREMENTS FOR DATA GENERATED	A20-1
20.2 DATA VALIDATION REQUIREMENTS FOR DATA GENERATED BY SUBCONTRACTOR LABORATORIES	A20-1

TABLE OF CONTENTS (CONTINUED)

21. RECONCILIATION WITH DATA QUALITY OBJECTIVES	A21-1
21.1 DQI DEFINITION AND EVALUATION.....	A21-1
21.2 DATA QUALITY ASSESSMENT APPLICATION	A21-3
21.3 DATA REPORT QA SECTIONS.....	A21-4

LIST OF FIGURES

2-1 Contract Organization.....	A2-1
17-1 Data Management and Data Tracking	A17-3

LIST OF TABLES

5-1 General Description of DQIs	A5-3
12-1 Sample Collection QC Measures, Frequency, and Control Limits.....	A12-2
12-2 Analytical QC Measures and Frequency	A12-4
15-1 Example of a Log for Tracking Supplies and Consumables.....	A15-1
18-1 Assessment Frequency.....	A18-5

ATTACHMENTS

1 Sample Data Sheets and Chain-of-Custody Forms	
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ACRONYMS

%RPD	Relative Percent Difference
%RSD	Relative Standard Deviation
ASC	Analytical Services Coordinator
ASP	Analytical Services Plan
CAR	Corrective Action Request
CERCLA	Comprehensive Environmental Response Compensation and Liability Act
COC	Chain-of-Custody
COC/TR	Chain-of-Custody/Traffic Report
COO	Chief Operations Officer
DQA	Data Quality Assessment
DQIs	Data Quality Indicators
DQOs	Data Quality Objectives
EPA	U.S. Environmental Protection Agency
HSP	Health and Safety Plan
ITD	Information Technology Division
LCS	Laboratory Control Samples
M&TE	Measurement and Test Equipment
MQIs	Measurement Quality Indicators
MQOs	Measurement Quality Objectives
MS/MSDs	Matrix Spike/Matrix Spike Duplicates
NIST	National Institute of Standards and Technology
PE	Performance Evaluation
PIDs	Photo Ionization Detectors
PRP	Potentially Responsible Party
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QPs	Quality Procedures
RPM	Remedial Project Manager
SARA	Superfund Amendments and Reauthorization Act
SOPs	Standard Operating Procedures
SOW	Statement of Work
TSOPs	Technical Standard Operating Procedures

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1. INTRODUCTION

This Quality Assurance Project Plan (QAPP) addresses the type and quality of data needed for environmental decisions and provides direction for collecting, assessing, and reporting those data for the Remedium Group, Inc. Contract work orders. Parametrix prepared this QAPP in accordance with U.S. Environmental Protection Agency (EPA) requirements in EPA Quality Assurance (QA)/R-5, EPA Requirements for Quality Assurance Project Plans, Final, March 2001, and guidelines in EPA QA/G-5, EPA Guidance for Quality Assurance Project Plans, December 2002.

This document provides the basis for developing work-order-specific QAPPs. Updates or revisions to this plan will occur at least annually to accommodate:

- New direction or guidance from the client.
- New requirements of work-order-specific work assignments.
- Corrective actions and lessons learned through assessments of the contract Quality Assurance Program.

Document control information is provided on each page of this QAPP. The header at the top of each page lists the revision number; the footer at the bottom of each page lists the revision number date. This information will also be provided with each work-order-specific QAPP to ensure that all appropriate personnel on the distribution list are provided with the most current approved version of the QAPP.

As shown in Figure 2-1, the Parametrix Work Order QA Managers and QA Officer are integrated into the project organization, but have an independent reporting relationship to their immediate supervisors. Subcontractor Work Order QA Managers will report to the Parametrix Work Order QA Managers. Section 2.1.3, below, outlines the QA requirements that Parametrix will require of its subcontractors on the contract.

Throughout the contract, the Parametrix QA Officer, Work Order QA Managers, and Subcontractor QA Managers will communicate regularly on all QA/QC requirements. The Parametrix QA Officer and Work Order QA Managers will specifically work closely with Subcontractor QA Managers to ensure that any QA concerns are communicated, addressed, and resolved.

As shown on Figure 2-1, the QA communication network can involve some or all of these parties, depending on the QA function being addressed.

2.1.2 Program and Work Order Management Staff

The Parametrix Project Manager or designee (Deputy Project Manager), Work Order Managers, and other supervisory staff are responsible for ensuring that relevant quality procedures (QPs) are implemented by themselves and their staff. Specific responsibilities include:

- Ensuring that their staff members know the quality and technical requirements for each work order.
- Ensuring that adequate resources to meet the contract quality requirements are included in work order budgets.
- Consulting with the assigned QA staff regarding quality requirements.
- Ensuring that QA sections are prepared for work plans and data reports.
- Ensuring that technical and quality assurance review procedures are implemented.
- Ensuring that QA review requirements are met.
- Scheduling and conducting self-assessments.
- Cooperating during internal and external QA audits.
- Performing subcontract management and oversight.
- Reporting regularly to the Parametrix Principal-in-Charge and/or COO.

2.1.3 Subcontractor QA Requirements

2.1.3.1 Parametrix Subcontractors

Parametrix will require from all Team Subcontractors:

- A commitment to implement the Parametrix QA program described in the contract Quality Management Plan (QMP) and/or QAPPs as it applies to their firm's contract work.
- A Subcontract QA Manager and Work Order QA Managers (as necessary).

- The submission of QA/QC procedures and/or SOPs that are specific to the types of technical work anticipated under the subcontract, and that are not otherwise included in the work-order-specific QAPP.
- Implementation of an internal corrective action system.
- Agreement to corrective actions required by Parametrix.
- Implementation of a documented technical review system.
- Regular QA summary reports to the Parametrix QA Officer.

2.1.3.2 Other Subcontractors

QA/QC requirements for other subcontractors will vary depending on the technical work and requirements for individual work orders. Therefore, QA/QC requirements will be written into individual subcontract documents. The appropriate elements from the list in Section 2.1.3.1, above, will be included.

2.2 QUALITY MANAGEMENT RESPONSIBILITIES/AUTHORITIES

2.2.1 Parametrix QA Officer

The Parametrix QA Officer is responsible for developing, implementing, and assessing the implementation of the overall contract quality program. The QA Officer is independent of the contract technical and management staff and has full access to and reports to the Parametrix COO. The QA Officer thus has the authority to review and identify problems and to bring corporate resources to bear on solving problems, if necessary. If disputes arise with respect to quality matters, the QA Officer, in consultation with the COO, is the final arbitrator of the dispute on behalf of Parametrix.

2.2.2 Parametrix Contract Management Staff

The Project Manager, Work Order Managers, and other supervisory staff are responsible for ensuring that relevant QPs are implemented by themselves and their staff. They are supported by and have full access to Parametrix management in carrying out their responsibilities. Their specific responsibilities include:

- Ensuring that their staff members know the quality and technical requirements for each work order.
- Ensuring that adequate resources to meet contract quality requirements are included in work order budgets.
- Consulting with the assigned QA staff regarding quality requirements.
- Ensuring that QA sections are prepared for work plans and data reports.
- Ensuring that technical review procedures are implemented on all technical documents.
- Ensuring that QA review requirements are met.
- Scheduling and conducting self-assessments.
- Cooperating during internal and external QA audits.
- Suggesting improvements to quality systems, documents, and procedures.

- Devising corrective actions to resolve problems and ensuring completion of corrective actions.
- Reporting regularly to the Parametrix QA Officer.
- Communicating directly with the Parametrix QA Officer if a quality-related concern is not adequately addressed through the normal, administrative chain of command.
- Considering each employee's quality implementation during performance appraisals.

2.2.3 Work Order QA Managers

The Work Order QA Managers are independent of the contract technical and management staff and report to the Parametrix QA Officer. They have full authority to make quality-related decisions with respect to work order work. This specifically includes the authority to stop work order work if they identify issues or problems that may affect the quality of the work being performed, and the authority to resolve quality issues through the normal administrative chain of command. The Work Order QA Managers are further responsible for:

- Actively tracking the implementation of the QAPP on a work order basis and consulting with Work Order Managers. QAPPs must be approved by the Client and regulatory agency with primary oversight responsibility prior to the start of any fieldwork. The only exception will be for emergency response actions. An emergency response action is defined as one where the response contractor must mobilize to the site in less than 14 days after being notified that they need to conduct an emergency response activity. In this instance, however, Regulatory Agency Staff need to be notified that sampling activity may occur and that the QAPP will follow within 30 days of the project start.
- Working with work order staff to select appropriate quality measures for their work order work.
- Interfacing with the primary regulatory agency on task-specific QA issues.
- Interfacing with and providing oversight to subcontractor QA Managers.
- Training technical staff in task-specific QA requirements.
- Carrying out responsibilities identified in work-order-specific QAPPs.
- Reviewing data reports for QA requirements.
- Conducting or arranging work-order-specific audits or surveillances.
- Initiating and following up on corrective action requests (CARs).
- Reporting regularly to Work Order Managers.
- Overseeing data review, validation, and assessment of data quality objectives (DQOs) and data quality indicators (DQIs).

2.2.4 Subcontractor QA Managers

Each Subcontractor QA Manager also functions independently of his/her technical and management staff. They have full authority to make quality-related decisions with respect to their assigned work order work. This specifically includes the authority to stop work order subcontract work if they identify issues or problems that may affect the quality of the work being performed, and the authority to resolve quality issues through the normal administrative

chain of command. In this regard, they have full access to and report to the Work Order QA Manager. They are also responsible for the following tasks within their firm:

- Requiring their staff to implement the contract QA program.
- Meeting the requirements of their contract assignment.
- Supporting any necessary corrective actions.
- Carrying out responsibilities identified in work-order-specific QAPPs.
- Reporting regularly reporting to the Work Order QA Manager.

Other responsibilities and roles associated with the contract are addressed in work orders or QAPPs.

2.2.5 Analytical Services Coordinator

The Analytical Services Coordinator is assigned to all work orders requiring analytical laboratory services. The Analytical Services Coordinator shares certain responsibilities with the Work Order QA Manager, specifically, those dealing with analytical services, as follows:

- Working with Work Order Managers, QA staff, and internal project staff to define appropriate QC requirements that will meet the DQOs for each work assignment.
- Reviewing and approving all work order QAPPs.
- Assisting with the preparation, review, and approval of laboratory Statements of Work (SOWs) and procurement packages for subcontractor laboratories in accordance with the Analytical Services Plan (ASP).
- Scheduling sample receipt with subcontractor laboratories.
- Communicating with Work Order Managers and field staff regarding the laboratories that are assigned to the sampling event.
- Communicating with Work Order Managers and field staff to ensure that sample management and documentation requirements are being met during field operations.
- Submitting sample trip reports as necessary.
- Tracking all samples from time of scheduling to receipt of validated data by the project team.
- Ensuring that changes in procedures are communicated to project staff promptly.
- Conducting or arranging for subcontractor laboratory audits or surveillances, including laboratory performance evaluation (PE) samples.
- Overseeing and/or conducting data validation from subcontractor laboratories.

2.2.6 Field Operations Coordinator

A Field Operations Coordinator/Field Team Leader may be assigned to projects requiring a large field effort. The responsibilities of the Field Operations Coordinator/Field Team Leader include:

- Coordinating the field planning effort and leading the field planning meeting.

- Ensuring that field personnel successfully follow and implement the QAPP, Health and Safety Plan (HSP), and Standard Operating Procedures (SOPs) developed for the work order.
- Ensuring that quality data are collected in the field.

2.2.7 All Employees

All Parametrix employees are responsible for performing quality work that meets or exceeds Parametrix and Client requirements. These requirements are defined during the quality planning described in Section 3.0 of this QAPP. However, specific responsibilities include:

- Knowing the requirements for each work order effort.
- Using appropriate quality measures for each work order effort.
- Maintaining familiarity with the contract QMP and work-order-specific QAPPs.
- Suggesting modifications and improvements to quality systems, documents, and procedures.
- Notifying an immediate supervisor, the QA Officer, the Work Order QA and QC Manager, the Work Order Manager, or the Project Manager/Deputy Project Manager of quality problems and proposing suggestions for solving them. Employees always have immediate access to supervisors and managers through personal contact, phone, fax, and email and are encouraged to contact these individuals, as necessary.

2.2.7.1 Policy on Waste, Fraud, and Abuse

All Parametrix employees, and subcontractor employees, are responsible to report any observed instances of waste, fraud, and abuse pursuant to EPA Manual 6500, "Functions and Activities of the Office of the Inspector General," January 22, 1985, and 40 CFR Part 3. Specifically, Parametrix and subcontractor employees are responsible for promptly reporting instances of, and information on, any known or suspected violation of law, rules, or regulations; mismanagement; gross waste of funds; abuse of authority; or substantial and specific danger to the public health and safety. Employees should report such instances to their supervisors, the Parametrix Quality Assurance Officer or, if necessary, directly to the COO.

3. PROBLEM DEFINITION/BACKGROUND

Under the contract, Parametrix will provide professional, technical, and management services to Remedium to support investigation and cleanup activities at the Libby Montana Site under the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), and other laws to help address and/or mitigate endangerment to the public health, welfare, or environment. The services under this contract with Remedium will be performed wholly in EPA Region 8.

Contract services will include:

- Assistance in negotiations with regulatory agencies.
- Preparation of data reports.
- Preparation of planning documents.
- Ecological sampling activities (aquatic, terrestrial).
- Biological research (necropsies, etc.).
- Toxicity testing and related research with site biotic/abiotic media.

Under the contract, Remedium will issue individual work orders or make specific requests for specific work. Parametrix will incorporate information, such as decisions to be made, actions to be taken, and expected outcomes of the assignment, into each work-order-specific work plan (if needed) and QAPP (unless otherwise provided to Parametrix).

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4. WORK ORDER DESCRIPTION

This section discusses general techniques for defining work order objectives and activities. According to EPA QA/R-5, a QAPP must provide sufficient information to demonstrate that:

- The project technical and quality objectives (i.e., DQOs, when used) have been identified and agreed upon.
- The intended measurements or data acquisition methods are appropriate and consistent for achieving project objectives.
- Assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained.
- Any limitations on the use of the data can be identified and documented.

To satisfy these information needs, work-order planning documents will identify the types of activities to be conducted, including measurements that will be made (with associated quality assurance/quality control goals), procedures to be implemented, and timetables for collecting the measurements. Each work-order document will be developed, based on the requirements of this generic QAPP (unless a QAPP document is provided directly to Parametrix for implementation). In developing work-order-specific QAPPs, Parametrix will follow the systematic planning process delineated in EPA's Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4, Final, February 2006. This seven step process is described in detail in Section 5.

Work-order-specific information, such as site conditions, DQOs, methods, deliverables, schedules, etc., will be presented in work-order-specific QAPPs (unless the QAPP with this information is provided directly to Parametrix). Generally, work orders will include some of the following activities:

- Listing measurements that are expected during the course of the work assignment and the measurement methods that will be used. Use of approved methods to define chemical, biological, toxicological, geophysical, radiochemical, and other measures. Actual parameters and measurements used will depend on specific work order goals and site requirements.
- Listing applicable technical, regulatory, or project-specific quality standards, criteria, or objectives. Each work-order-specific QAPP will define the sampling, measurement, standard operating procedures, and requirements specific to the work order objectives.
- Providing specific or unique calculations, equations, or algorithms to be used. Work-order-specific QAPPs will discuss any statistical techniques or applications that will be used to assess data. If a QAPP lacking calculations/statistics is provided directly to Parametrix for implementation, all calculation methods will be specified in the data report.
- Providing Technical Standard Operating Procedures (TSOPs) that address sample labeling, collection, storage, transfer, and disposal. Additional SOPs will address activities such as field instrument calibration, field equipment decontamination, well development, sample collection, etc. Technical SOPs will be generated (unless provided) on a work order basis, as necessary and as negotiated during project scoping.

- Developing quality-reviewed deliverable documents, such as work plans, QAPPs, feasibility studies, data reports, risk assessment reports, construction documents, cost analyses, site inspection reports, treatability studies, etc. All documents will be reviewed and approved by technical reviewers experienced in the subject area they are reviewing.
- Providing quality-reviewed procurement documents for professional services, such as laboratory SOWs and procurement packages as described in the ASP (Appendix B of the QMP).

Each work order will be assigned to a Parametrix Work Order Manager by the Project/Deputy Project Manager. Depending on the requirements and DQOs of the work order assignment, Parametrix will assign experienced personnel in critical technical areas. Each work-order-specific work plan and QAPP will contain a schedule for the work to be performed. Significant milestones will be emphasized to ensure that contract objectives and DQOs are addressed within the required time frame.

5. QUALITY OBJECTIVES AND CRITERIA

Unless otherwise provided, Parametrix will develop DQOs for each work-order-specific QAPP and will implement these DQOs according to EPA's Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4, Final, February 2006, to provide data of known and appropriate quality for each work assignment.

The DQO process is a seven-step planning approach to developing sampling designs for data collection activities that support decision making. It provides a systematic procedure for defining the criteria that a data collection design should satisfy, including when to collect samples, where to collect samples, the tolerable level of decision errors for the study, and how many samples to collect. The DQO process consists of the following seven steps. The output from each step influences the choices that will be made later in the process:

- **Step 1:** State the Problem – Give a concise description of the problem that necessitates the study. Identify the leader and members of the planning team. Develop a conceptual model of the environmental hazard to be investigated. Determine resources, including budget, personnel, and schedule.
- **Step 2:** Identify the Goal of the Study – Identify principal study question(s). Consider alternative outcomes or actions that can occur upon answering the question(s). For decision problems, develop decision statement(s), organize multiple decisions. For estimation problems, state what needs to be estimated and key assumptions.
- **Step 3:** Identify Information Inputs – Identify types and sources of information needed to resolve decisions or produce estimates. Identify the basis of information that will guide or support choices to be made in later steps of the DQO Process. Select appropriate sampling and analysis methods for generating the information.
- **Step 4:** Define the Boundaries of the Study – Define the target population of interest and its relevant spatial boundaries. Define what constitutes a sampling unit. Specify temporal boundaries and other practical constraints associated with sample/data collection. Specify the smallest unit on which decisions or estimates will be made.
- **Step 5:** Develop the Analytic Approach – Specify appropriate population parameter(s) for making decisions or estimates. For decision problems, choose a workable Action Level and generate an “If ... then ... else” decision rule which involves it. For estimation problems, specify the estimator and the estimation procedure.
- **Step 6:** Specify Performance or Acceptance Criteria – For decision problems, specify the decision rule as a statistical hypothesis test, examine consequences of making incorrect decisions from the test, and place acceptable limits on the likelihood of making decision errors. For estimation problems, specify acceptable limits on estimation uncertainty.
- **Step 7:** Develop the Detailed Plan for Obtaining Data – Compile all information and outputs generated in Steps 1 through 6. Use this information to identify alternative sampling and analysis designs that are appropriate for the intended use. Select and document a design that will yield data that will best achieve the performance or acceptance criteria.

Even though the DQO process is depicted as a linear sequence of steps, in practice, it is iterative; the outputs from one step may lead to reconsideration of prior steps. This iteration is encouraged since it will ultimately lead to a more efficient data collection design.

The DQO process shall be implemented during the planning stages of tasks that involve data collection. The DQO process is applicable to data obtained directly (e.g., through a field sampling and analysis program) and for data obtained indirectly (e.g., previously collected information in historic databases). Personnel involved in all or parts of the DQO development process will generally include the Work Order Manager, the Project or Deputy Project Manager, the Work Order QA Manager, the Analytical Services Coordinator, and technical team specialists in data collection design and statistics. When initiating DQO development, consideration will be given to:

- Number of samples taken for each matrix.
- Eventual use of the analytical data by regulatory authorities.
- Level of contamination and range in concentrations expected at the sampling site(s).
- Extent of contamination expected at the sampling site(s).
- Project schedule and any constraints on field sampling seasons.
- Whether data are collected directly or non-directly. (Acquisition and evaluation of data obtained non-directly is addressed in Section 16.) The DQOs and DQIs should be comparable for data collected directly and indirectly when tasks involve both types of data.
- Budgetary constraints associated with the sampling site(s).

DQOs are also used to assess the quality and usability of data (new or existing) in relation to their intended use. Data quality and usability are evaluated in terms of performance criteria (or acceptance criteria, in the case of previously collected data). Performance and acceptance criteria are expressed in terms of DQIs. The principal indicators of data quality are precision, accuracy, bias, sensitivity, completeness, comparability, and representativeness. Measurement quality objectives (MQOs) are established during the DQO process and represent the acceptance thresholds or goals for the task's data, based on the individual DQIs for each matrix and analyte group. Table 5-1 provides a general description of DQIs. DQIs are discussed in more detail in Section 21, Reconciliation with Data Quality Objectives.

Each work-order-specific QAPP will tabulate DQIs along with associated Measurement Quality Indicators (MQIs) (i.e., acceptance thresholds or goals) for each matrix and analyte group. Acceptance criteria for DQIs will be established on a work-order-specific basis. For example, certain tasks, such as those involving risk assessment, may have a higher percentage requirement for data usability than other tasks, such as those requiring field screening. The development of acceptance criteria for DQIs will be based on the following:

- Fulfilling DQOs.
- Meeting QC acceptance criteria established in specific analytical methods.
- Other guidance documents as appropriate.

Table 5-1. General Description of DQIs

DQI	Description
Precision	A measure of agreement among repeated measurements of the same property under identical conditions. Usually assessed as a relative percent difference (%RPD) or relative standard deviation (%RSD) from duplicate or replicate measurements.
Accuracy	A measure of the overall agreement of a measurement to a known value. Usually assessed as percent recovery from matrix spike or reference material measurements.
Bias	The systematic or persistent distortion of a measurement process that causes errors in one direction. Usually assessed with reference material or matrix spike measurements.
Sensitivity	The capability of a method or instrument to meet prescribed reporting limits. Assessed by comparison with risk-based reporting limits, method reporting limits, instrument reporting limits, or laboratory quantitation limits, as appropriate.
Completeness	A measurement of the amount of valid data needed to be obtained for a task. Assessed by comparing the amount of valid data to the amount required to meet DQOs.
Comparability	A qualitative term that expresses the measure of confidence that one data set can be compared to another. Assessed by comparing sample collection and handling methods, sample preparation and analytical procedures, holding times, reporting units, and other QA protocols.
Representativeness	A qualitative term that expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variation at a sample point, or environmental condition. Assessed by verifying representative conditions and by comparing anticipated sample variability with variability shown in field replicate samples.

The outputs of the DQO process will be used to develop other sections of the work-order-specific QAPP, including sample/analysis design, data validation, and data usability. Specifically, DQO outputs will be used to:

- Decide the action levels or standards, including the reporting limits and data reporting units. These requirements determine which laboratories have the capabilities to perform chemical, biological, geophysical, radiochemical, or other analyses, as required. Each work-order-specific QAPP will cite the particular methods to be used.
- Specify the statistical form of data to be used when compared against actual action levels or standards. Work-order-specific QAPPs will summarize the statistic(s) to be employed for the generated data.
- Determine the acceptable level of confidence in the data needed to meet the work order requirements. Each work order will determine the actual amount of uncertainty associated with the data being generated and will assess those uncertainties against the established tolerable limits. For example, data will be evaluated statistically to ensure that measurement errors are managed sufficiently to meet the tolerable decision error rates. Each work-order-specific QAPP will also establish the acceptable level of confidence in data in terms of (1) quantitative DQIs of precision, accuracy/bias, sensitivity, and completeness; and (2) qualitative DQIs, which

examine representativeness and comparability. DQIs will be evaluated through data validation procedures to assess data usability and completeness.

Validation and verification methods for DQIs are presented in Section 20. Evaluation of data packages against DQOs and DQIs (i.e., Data Quality Assessments [DQAs]) is addressed in Section 21. To ensure that DQOs are being maintained, procedures such as audits, internal QC checks, and corrective actions, as described in Section 18 of this QAPP, will be implemented.

6. PERSONNEL TRAINING/CERTIFICATION

6.1 TRAINING AND QUALITY

Quality work can be expected from employees when they are thoroughly trained and understand the technical and contract-specific requirements of their work. As a matter of policy, all Parametrix and subcontractor staff will be qualified and trained to perform their assignments properly and safely. These qualifications may be met by combinations of education, experience, and specific training. Employees are hired based on their qualifications and abilities, but certain work orders may require that additional training be conducted. Categories of training include:

- Project Management.
- Quality Assurance.
- Health and Safety.
- Technical Skills.
- Work order-specific training.

Project and Work Order Managers receive initial project management training and regular training updates as part of Parametrix's corporate "Project Delivery" training program. This training encompasses all general aspects of project management, as well as specific requirements and procedures.

Work Order Managers and Parametrix employees assigned to the contract receive QA program training on the contract-specific QMP and QAPPs. This training includes regular training updates on QA program revisions, QA tips, procedures, and protocols. On-the-job QA training also occurs during staff and management interaction on QA reviews, project assessments, and corrective actions.

Identified QA staff (Work Order QA Managers and others) receive additional outside training in QA procedures through participation in training courses or other regional and national conferences through professional organization affiliation.

QP 1.1 specifies the process, responsibilities, procedures, and documentation required for training. All of the items discussed below are covered in more detail in QP 1.1.

6.2 TRAINING NEEDS ASSESSMENT AND IMPLEMENTATION

It is the responsibility of the Project/Deputy Project Manager and Work Order Managers to:

- Ensure that work is performed by properly trained, qualified individuals, including field operations, for appropriate and necessary health and safety training.
- Select appropriate personnel by reviewing resumes and qualifications.
- Determine if additional training, or retraining (e.g., based on changing requirements or corrective actions), is required.
- Specify and arrange for additional training or retraining as required.
- Ensure that proper documentation of all training is maintained in the Parametrix corporate office and designated work order files.

Staff will maintain their qualifications through regular and additional training, as necessary, to meet changing quality requirements or system upgrades.

6.3 TRAINING DOCUMENTATION

As a matter of policy, Parametrix maintains documentation of all corporate-sponsored and other training that involves Parametrix staff. Documentation of training for subcontractor staff will not be maintained unless specifically required by a work-order-specific work plan or QAPP. Record keeping requirements and forms for the indoctrination and training process are provided in QP 1.1. The Project/Deputy Project Manager and the QA Officer will ensure that training requirements are being satisfied through the assessment of training records.

7. DOCUMENTS AND RECORDS

This section identifies procedures for control, storage, retrieval, and disposition of documents and records.

7.1 DOCUMENTS

Documents include information in any medium, including, but not limited to: electronic or paper copy, computer storage media, audio or audio tape, photograph, overhead, or photographic slide. Document control is defined as the process of ensuring that documents, including revisions, are reviewed for adequacy, approved for release by authorized personnel, and distributed for use by the personnel performing the activities. Standard procedures for document preparation, review, approval, distribution, and control are provided in QP 3.1 of the QMP.

Each work-order-specific Work Plan and QAPP will define which documents, records, and electronic files are critical to the project and what information needs to be included in reports and other deliverables. The different reports, studies, and other deliverables that may be developed under this contract were described in Sections 3 and 4.

Distribution of reviewed and approved documents will also be determined on a work order basis by the Work Order Manager, in consultation with the Project Manager. As discussed in the next section, the Administrative Assistants are responsible for handling the proper distribution of documents, including updates or revisions. Document control information is provided on the footer of each page of this generic QAPP and will also be provided with each work-order-specific QAPP. The Administrative Assistant will keep a tracking log with the name and address of each recipient on the distribution list. The tracking log will also include the date of the revision, the revision number, and the section(s) revised. These document control procedures will ensure that all appropriate personnel on the distribution list are provided with the most current approved version of the QAPP.

7.2 RECORDS

A record is defined as a completed, validated document and/or other material. A document becomes a record once it is completed, reviewed, and validated. Examples include Work Plans, QAPPs, deliverables, reports, correspondence, field notes, laboratory data, computer storage media containing electronic databases, and QA/QC documents. Records control is the process of identifying records and providing ready retrieval, storage, and protection of records. Procedures for records control (for both hard copy and electronic files) are provided in QP 3.4 of the QMP.

At the beginning of the work order, the Work Order Manager will develop a list of documents or document types which will, over the course of the project, become records. The Contract and/or Work Order Administrative Assistants are responsible for the work order files (both hard copy and electronic files). These individuals are also responsible for implementing a formal records control system and for handling distribution of documents and records, including updates or revisions. The Work Order Manager is responsible for working with Administrative Assistants to ensure that records are handled in accordance with the records control requirements.

Records will be stored in the Parametrix office responsible for performing the work order activities, unless other arrangements have been made by the Project Manager. Records will be stored in enclosed file cabinets, on document storage shelving, or in file storage boxes. If

specified by the Project/Deputy Project Manager, records will be stored in locked file cabinets or locked storage area. Only Parametrix employees and consultants will have keys to the office suite. Electronic files will be stored in a central network location, which is backed up daily to prevent loss of information. When electronic files are archived, they will be transferred to CDs. Three CD copies of the archived files will be made and stored in different locations to prevent loss of information.

Retention and ultimate disposition of records will be determined in consultation with the Client. Record disposition includes transferring records to the Client and discarding records. At the completion of the agreed-upon retention period, records will be transferred or discarded, or the retention period will be extended. Records to be transferred or discarded will be inventoried, if requested or required by the Project/Deputy Project Manager. Parametrix will maintain inventory lists as evidence of action taken.

8. SAMPLING PROCESS DESIGN

8.1 GENERAL SAMPLING PROCESS DESIGN

This section outlines, in general terms, the sampling process design to be used in work order assignments. Essential elements, including sample types, frequencies, matrices, sampling networks, measurements, parameters, etc., will be discussed briefly here, and presented in greater depth in work-order-specific QAPPs. Those involved in the sampling process design will generally include the Work Order Manager, the Remedial Project Manager (RPM), the Work Order QA Manager, and technical team specialists in data collection design and statistics.

The sample process design should include or consider the following:

- A clear definition of the scientific and regulatory objectives for sampling.
- The end use of the data.
- Critical and noncritical measurements.
- A description of the techniques or guidelines used to select sampling sites.
- A description of the sample types (air, water, soils, sediment, biota, etc.).
- A discussion of the sampling strategy. Descriptions of the type of strategy (e.g., simple, stratified, or systematic random sampling) and the statistical basis for that strategy. Description of sampling point locations and sampling frequencies or sample counts should be included.

8.2 SAMPLING STRATEGIES

Work-order-specific QAPPs will discuss the particular sampling strategies to be employed for the various media (soils, sediments, water, etc.) associated with the site. The guidance in EPA QA/G-5s, Guidance for Choosing a Sampling Design for Environmental Data Collection, 2002, will be referenced in selecting an appropriate sampling strategy unless other technical guidance is identified. The various sampling strategies available can be grouped into two basic categories: classical statistical strategies and nonstatistical strategies. A description of each category is provided below.

Classical Statistical Sampling

Classical statistical sampling includes the following:

- **Simple Random Sampling** – This is the most basic statistical approach and is usually applied when minimal site background information (e.g., past practices, use of hazardous material) is available and when visible signs of contamination are not evidenced during the initial site survey.
- **Stratified Random Sampling** – This type of sampling is used for investigations of large sites that encompass a number of soil types, topographic features, or land uses. The site is divided into different sampling areas that are internally homogenous, based on existing data and background information.
- **Systematic Grid Sampling** – This is the most common statistical sampling strategy. Samples are collected at predetermined, regular intervals (i.e., within a grid pattern), with the location of the first sampling point selected at random and all subsequent

sample locations determined using a systematic pattern from that point. This approach is typically used when a large site (e.g., measured in acres) must be sampled to characterize the presence and distribution of contaminants.

- **Systematic Random Sampling** – This approach is essentially the same as the systematic grid, except that the actual sampling within the grid pattern is random rather than predetermined.
- **Hot-Spot Sampling** – This is a systematic grid sampling strategy tailored to search for hot spots. This application is used for sites where background information or site survey data indicate that hot spots may exist. This strategy does not take into account spatial variability of media. Tradeoffs between number of samples, chance of missing a hot spot, and hot spot size/shape must be carefully weighed.
- **Geostatistical Sampling** – This approach is used when representative sampling locations are chosen based on spatial variability of media. Resulting data are analyzed using geostatistical algorithms to create contour maps of the contaminant concentrations and the precision of concentration estimates. This approach is more appropriate than other statistical sampling strategies because it takes into account spatial variability of media. It is especially applicable to sites where the presence of contamination is unknown. Previous investigation data must be available, and such data must be shown to have a spatial relationship.

Nonstatistical Sampling

- **Biased Sampling** – This nonstatistical approach may be used when sampling locations are chosen based on available information. This usually applies for sites with specific, known contamination sources. However, contaminated areas can be overlooked if they are not indicated by background information or visual signs of contamination. This is best used if combined with a statistical approach, depending on the project objectives.
- **Judgmental Sampling** – This approach is used by an individual who subjectively selects sampling locations that appear to be representative of average conditions. This usually applies to homogeneous, well-defined sites. This approach is not usually recommended because of bias imposed by the individual, especially for final investigations. The sampling design should provide data that are representative of the site conditions and the parameters of interest. Representativeness expresses the degree to which sample data accurately and precisely represent a characteristic of a population, environmental condition, or parameter variations at a sampling point. Representativeness is addressed by selecting sampling techniques, sample frequencies, sampling locations, sampling time periods, and the size of the sampling area that will provide representative data. Sampling locations can be biased (based on existing data, instrument surveys, observations, etc.) or unbiased (completely random or stratified-random approaches). The schedule for sampling will often be dependant on the need to provide representative data with respect to seasonality, tidal influences, diurnal variability, etc. The number or frequency of samples will often depend on the sample design (e.g., probability-based or judgmental).

8.3 DETERMINATION OF SAMPLING CRITERIA

The rationale used to determine sampling locations, size of the sampling area, number of samples, sampling schedule, etc. will be explicitly explained in the work-order-specific

QAPPs. Sampling locations determined by grid, GPS, or existing structures will be shown on maps of the site. The work-order-specific QAPP will also specify the types of samples, such as a grab or composite sample, and the specific media to be sampled (e.g., air, water, soil, sediment).

Key questions to consider in selecting the appropriate sampling design are:

- Can samples or measurements be taken according to a probability-based design?
- What are the budgetary and scheduling constraints of the work order?
- Will the data need to be comparable to previously collected data?
- Do all samples need to be taken simultaneously?
- Are there site access constraints?
- Is a grid pattern for sampling practical, given the specific site conditions?
- Can samples be composited?
- Which media and contaminants are considered to be critical, and which are considered to be secondary (e.g., for trend analysis)?

Upon selecting a preferred sampling design, the planning group will establish and document the following information in the work-order-specific QAPP:

- Number of samples, by type and media.
- Sample locations.
- Number of samples at each location.
- Sampling schedule.
- Number and type of samples to make a composite (if appropriate).
- Number and type of QC samples (to be coordinated with the DQO process).
- Location and types of samples to serve as replacement or contingency samples that are essential to the integrity of the project (e.g., contingency locations in the event that certain sampling locations become inaccessible).
- Which samples and constituents are critical and which are secondary or for informational purposes.

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9. SAMPLING METHODS REQUIREMENTS

Proposed sampling methods will be consistent with EPA (and/or other oversight agency) guidance documents and SOPs. As appropriate, the EPA document, A Compendium of Superfund Field Operations Methods, will be consulted. When an EPA method, procedure, and/or technique is not available (such as in the case of using special sampling equipment or unusual analytes), Parametrix will define and develop new SOPs. A new SOP will include performance criteria that are consistent with work order DQIs, so that methods can be assessed during data validation. Before use, new SOPs will be reviewed for compliance with EPA QA/G-6, Guidance for Preparing SOPs, March 2001, and other applicable EPA guidance.

Sampling methods specifying sampling procedures, decontamination procedures, sample volumes, and sample containers will be developed and documented in work-order-specific QAPPs. Specifically, the work-order-specific QAPP will include the following, as appropriate:

- SOPs that anticipate potential field conditions and that link procedures and order of preference to critical data needs and the field conditions encountered.
- Specific sampling procedures to be used, incorporated by reference in the case of standard EPA-approved procedures, or by appending the entire procedure in the form of SOPs in the case of nonstandard procedures. Standard methods for sample splitting, sample compositing or homogenizing, and sample filtering (e.g., for dissolved metals analysis) will be included, as appropriate. Nonstandard methods should only be used in the event that standard EPA methods are impractical or inappropriate for specific site conditions.
- A list of sampling equipment and support facilities (e.g., scoops, spoons, hand augers, well pumps, field trailer). When equipment is to be used at more than one location, the QAPP will include SOPs detailing equipment cleaning procedures to prevent cross contamination of samples. Procedures in the form of SOPs will also be included for proper handling and disposal of decontamination byproducts.
- Containers used for sample collection, transportation, and storage for each sample type, and the supplier of the containers. The appropriate type and volume of container are generally specified by the standard analytical method to be used on the sample. As appropriate, special container preparation or cleaning procedures will be provided, as well as a description of any necessary support facilities for container storage (e.g., wind shelter, secured area).
- Sample preservation methods and holding times, including specific procedures, reagents, equipment, supplies, etc., required for field sample preservation. This will also include the specific time considerations for shipping samples promptly to the laboratory, and the specific sample storage conditions and times. The appropriate preservatives and holding times are generally specified by the standard analytical method to be used on the sample. If necessary, special SOPs for nonstandard methods will be developed and approved as described earlier.
- As appropriate, procedures and equipment for in situ or continuous monitoring (e.g., continuous water level measurement or continuous pH measurements). Procedures will include how instruments and equipment are to be deployed and operated, and how instruments should store and process data.

- Contingency plans for alternative sample locations and extra supplies of equipment and sample containers. Alternative sample locations will have been identified during the sampling design process. Sufficient supply of extra equipment, sampling containers, preservatives, coolers, etc. will be included as a backup.

The Work Order Manager and Field Operations Coordinator/Field Team Leader will ensure that all field personnel review and understand sampling methods prior to initiating fieldwork. Field sampling activities, as well as any problems encountered and any corrective actions, will be documented by Parametrix field personnel in field notebooks. If problems are encountered during sampling activities, they will be reported to the Work Order Manager or the Field Operations Coordinator/Field Team Leader. Corrective actions may include:

- Initiating contingency plans for alternative sample locations.
- Initiating contingency plans for use of extra equipment or sampling supplies.
- Reviewing and clarifying sampling procedures.

Parametrix field personnel will be trained on sampling methods and sampling documentation procedures, as needed. All training and instructions will be documented on site-specific training attendance forms or recorded directly in field notebooks. Following field activities, the field notebooks will be inspected by field personnel for accuracy, and will be stored as records in the work order file as described in Section 7.

10. SAMPLE HANDLING AND CUSTODY REQUIREMENTS

10.1 SAMPLE HANDLING AND DOCUMENTATION

Due to the potential evidentiary nature of samples collected during environmental investigations as part of this contract, sample possession must be traceable from the time samples are collected in the field until the analytical data are received and introduced as evidence in any legal proceedings. Work-order-specific QAPPs will provide the following (in the form of standardized SOPs) for both field and laboratory:

- A description of notebooks, sample data sheets, and procedures to be used in recording exact locations and ambient conditions associated with sample collection, possession, and analysis. See Attachment 1 of this QAPP for examples of sample data sheets.
- Examples of sample documentation forms, including sample labels, custody seals, and chain of custody (COC) forms. See Attachment 1 of this QAPP for example Chain-of-Custody/Traffic Report (COC/TR) forms for the contract.
- Labeling procedures, sample numbering system, and information to be entered on the forms (site names and sample locations will not be transmitted to the laboratory to avoid any real or perceived conflict of interest), including sample preservation, if any, and dates and times of sample transfer and analysis.
- Sample preservation methods and holding times (from collection to extraction) for each sample type, including specific procedures, reagents, equipment, supplies, etc. required for field sample preservation. This will also include specific time considerations for shipping samples promptly to the laboratory, specific laboratory receipt procedures (e.g., temperature checking or received samples), the specific sample storage conditions (e.g., temperature), and times. The appropriate preservatives and holding times are, in most cases, specified by the standard analytical method (e.g., SW-846, EPA Series 100–600). If necessary, special SOPs for nonstandard methods will be developed and approved as described in Section 9.
- Procedures for transferring and maintaining custody of samples. See also Section 17, Data Management, for further discussion on tracking the path of the data from generation to final use and storage.

Subcontractor laboratories will comply with the provisions above through their current laboratory QA Manual and the laboratory SOW. Procedures for developing laboratory SOWs and procuring laboratory services are provided in the ASP (Appendix B of the QMP).

In special cases, Parametrix may need to receive and/or maintain certain documents (e.g., data packages) under chain of custody. The Parametrix Project/Deputy Project Manager, in consultation with the Client, will identify documents requiring such treatment and develop the appropriate handling and documentation procedures.

The Work Order Manager, Analytical Services Coordinator, and Field Operations Coordinator will ensure that all field personnel review and understand sample handling and custody procedures prior to initiating fieldwork. Field sample handling and custody activities, as well as any problems encountered and any corrective actions will be documented by Parametrix field personnel in field notebooks. Following field activities, the field notebooks will be inspected by field personnel for accuracy, and will be stored as records in the work order file as described in Section 7.

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11. ANALYTICAL METHODS REQUIREMENTS

Each work-order-specific QAPP will include analytical parameters, analytical methods, reporting limits, instrumentation requirements, extraction procedures, method QC (blanks, surrogates, MS/MSDs, control samples, etc.), and required turnaround times necessary to meet the project DQOs and DQIs. The QAPP will also address as needed the appropriate requirements for split-sample analysis necessary to produce comparable analytical results. Analytical methods (e.g., SW 846, EPA Series 100–600) will be individually listed along with specific QC requirements, including holding times, preservative requirements, specific extraction methods, and sample volumes. Validation procedures for standard and nonstandard methods are covered in Section 20.

The appropriate analytical methods, required reporting limits, and laboratory QC deliverables will have already been established by the Work Order Manager, the Work Order QA Manager, the Analytical Services Coordinator (ASC), and other technical team members during the DQO planning process (see Section 5). Based on the required analytical methods, laboratory turnaround times, reporting limits, etc., the ASC will discuss the analytical services process and select the delivery mechanism that best meets the work order needs.

Parametrix will procure analytical services through a subcontract agreement and develop a subcontractor laboratory SOW detailing specific analytical methods, turnaround times, method performance standards, QC deliverables, and other requirements. Procedures for procuring analytical services and developing SOWs are provided in the ASP (Appendix B of the QMP). The ASP also includes procedures for ensuring analytical accountability, including financial penalties for failure to meet data quality requirements (or turnaround times), performance audits, performance evaluation samples, and corrective action procedures. These procedures are also applicable to mobile laboratories.

The laboratory SOW will also contain requirements for sample storage and disposal. The subcontractor laboratory will usually be required to maintain possession of environmental samples for no less than 60 days after delivery and acceptance of the sample data packages by Parametrix. Sample disposal and the disposal of used sample bottles/containers will be the responsibility of the laboratory. Any samples containing hazardous materials will be disposed of in accordance with all applicable laws and regulations governing disposal of such materials. The subcontractor laboratory will be responsible for the proper disposal of any on-site, laboratory-generated waste. When a standard analytical method is not available (such as in the case of unusual analytes), Parametrix will work with the analytical laboratory and the RPM to define and develop new SOPs. A new SOP will include performance criteria that are consistent with work order DQIs, so that methods can be assessed during data validation. The ASC will work in close communication with the subcontractor analytical laboratories to manage data and assess sampling and laboratory analysis performance. This communication will ensure that any problems associated with sample delivery, sample preparation, analysis, data evaluation, or reporting are addressed and resolved immediately. Communications associated with the sampling, analysis, and reporting process, as well as problems encountered and corrective actions, will be documented by the ASC and placed as a record in the work order files.

Monitoring of laboratory integrity and accountability will be accomplished through routine audits and surveillance performed by the Work Order QA Manager or the Analytical Services Coordinator. The responsibilities and procedures for planning, conducting, and closing out audits are provided in Section 18. Parametrix will also conduct data validation on analytical data from subcontractor laboratories to check the quality of the analytical results. Data validation will be conducted using a validation SOP, based on the sub-contracted laboratory's

SOW, analytical methods, and the work-order-specific QAPP. Data validation reports will detail any noncompliance and summarize the data usability.

If a deficiency is detected, every effort will be made to isolate the problem and determine its root cause. Immediate steps will be taken by the Work Order QA Manager or the ASC to correct or minimize the problem, so that the data validity is not endangered.

12. QUALITY CONTROL REQUIREMENTS

Each work-order-specific QAPP will specify the internal quality control (QC) measures that will be used to assess DQIs and ensure maximum valid data collection. Appropriate QC checks and frequency of use, control limits, and planned corrective actions if the control limits are exceeded will be provided, as appropriate. The control limits enable a field technician or laboratory analyst to identify a quality problem, and the planned corrective actions enable appropriate action to be taken quickly to prevent the accumulation of poor quality data. The QAPP will also note the requirement for a field planning meeting.

12.1 FIELD PLANNING MEETINGS

The work order work plan (if necessary) will define the number and frequency of field planning meetings for assignments involving fieldwork. The purpose of the field planning meetings will be to communicate to the project staff the requirements and procedures for the field effort, including the internal QC measures identified in the QAPP. The work order designated Field Operations Coordinator/Field Team Leader or the Work Order Manager will direct the planning session, which will be attended by the Work Order QA Manager and field staff.

During field planning meetings, the steps and activities of the fieldwork will be reviewed and discussed. The meetings will provide a forum for the project staff to identify any potential problems. Any problems identified during the field planning meeting will be documented and resolved. The field planning meeting agenda and attendance list will be maintained in the work order files.

12.2 INTERNAL QC CHECKS AND FREQUENCY FOR SAMPLE COLLECTION

Each sample collection activity will include checks on instrument and equipment calibration, as appropriate. In addition, blanks, duplicates and split samples, and spiked samples will be used to monitor sample handling procedures and the precision and accuracy of the measurement result as determined during the DQO development process. These performance measurements are also referred to as DQIs in Section 5. The work-order-specific QAPP will describe, in detail, how these QC samples will be created or collected. Deviations from the described procedures will be noted in field logbooks. In all cases, QC check samples supplied by Parametrix will be handled in the same way as field samples that are submitted to the laboratory for analysis.

Sampling QC checks will include some or all of the following:

- **Trip Blanks** – Deionized water added to clean sample containers off site and then brought to the field, but not opened, and then returned to the laboratory along with the samples. Trip blanks are used for VOC samples to check on possible contamination of samples during sample collection, handling, and transport.
- **Field Blanks** – Deionized water added to clean sample containers in the field to check on contamination introduced by sample collection activities, the sampling environment, or the sample container.
- **Spiked Samples** – In appropriate cases, known amounts of a particular constituent may be added to a field sample (or to a blank of deionized water) in the field to check on the accuracy of sampling and the effects of sample handling.

- **Split Samples** – Aliquots of one field sample placed into separate sample containers for analysis by different laboratories. Some potentially responsible party (PRP) oversight work may involve accepting splits from a PRP contractor who is collecting samples.
- **Duplicate Field Samples** – Individual samples collected at one field location, one after another, or on a random time frame, to provide precision information on the overall measurement. Time of collection must be noted to distinguish between the samples.

Sampling QC checks are amenable to a tabular format; Table 12-1 presents some general internal guidelines for QA/QC samples for field sampling programs under this contract. The table includes frequency of use and control limits for the QC checks, where applicable. The type of QC sample, collection frequency, and control limits will vary on a site-by-site basis. The actual type, frequency, and control limits for QC samples will be based on meeting the site-specific DQOs and DQIs, which are included in each work-order-specific QAPP. Procedures and formulas for calculating applicable QC statistics are given in Section 21. Data validation procedures for QC samples are provided in Section 20.

Table 12-1. Sample Collection QC Measures, Frequency, and Control Limits

QC Sample	Frequency	Control Limit
Trip Blanks (VOCs only)	Collect for each sample cooler containing VOC samples.	No contaminants present at concentrations greater than the reporting limit.
Field Blanks	Collect for each group of samples of each matrix per sampling day.	No contaminants present at concentrations greater than the reporting limit.
Equipment (rinsate) Blanks	Collect when sampling equipment is decontaminated and reused in field. Collect when sample collection vessel (e.g., bailer or beaker) is used.	No contaminants present at concentrations greater than the reporting limit.
Field Spike Samples	Prepare one per sample batch or 5 to 10 percent of all field samples by matrix, whichever is greater.	Organics: to be determined during DQO development on a work-order-specific basis.
Field Duplicate or Split	Collect one duplicate sample per day or 5 to 10 percent of all field samples by matrix, whichever is greater.	For organics, metals, and cyanide, establish allowable %RPDs during DQO development on a work-order-specific basis.

The work-order-specific QAPP will also include planned corrective actions to be taken if a problem is found. Field sampling data will be validated under the direction of the Work Order QA Manager. If QC samples are determined to be consistently outside of acceptance limits, every effort will be made to isolate the problem and determine its root cause. Immediate steps will be taken by the Work Order QA Manager to correct or minimize the problem so that the data validity is not endangered. Corrective actions may include, as appropriate:

- Audit and review sampling procedures with field personnel to ensure that approved methods are being followed.

- Check cleanliness of sampling equipment and containers.
- Audit and review equipment decontamination procedures to ensure that approved methods are being followed.
- Other actions deemed appropriate, based on patterns or trends in QC data.

Corrective actions will be documented by the Work Order QA Manager and placed as a record in the work order files.

12.3 INTERNAL QC CHECKS AND FREQUENCY FOR LABORATORY ANALYSIS

QC measures for subcontractor laboratories will be established in the laboratory SOW (see ASP [Appendix B of the QMP]) and in the work-order-specific QAPP. Some appropriate QC measures are defined below:

- **Method Blanks** – Method blanks contain all the reagents used in the preparation and analysis of samples, and are processed through the entire analytical scheme to assess spurious contamination arising from reagents, glassware, or other materials used in the analysis.
- **Calibration Check Samples** – This is a working calibration standard that is routinely used to check that the original calibration is still valid.
- **Laboratory Duplicates/Replicates** – One field sample is divided into two or more aliquots, and each aliquot is carried through the entire preparative and analytical scheme. The sample may also be received as double-volume samples from the field. The results are used to estimate the precision of the analytical procedures.
- **Spiked Samples** – Known amounts of a particular constituent are added to high-purity laboratory water or solvent or to a field sample. The percent recovery of the added amount is used to evaluate the accuracy of the analytical procedure. If laboratory water or solvent is spiked, the resulting sample may be called a Laboratory Control Sample (LCS). If a field sample is spiked, the resulting sample is called a matrix spike.
- **Laboratory Control Samples (LCSs)** – These samples are prepared from concentrates or National Institute of Standards and Technology (NIST) standard reference materials. The LCSs are used to establish that an instrument or procedure is in control. An LCS is normally carried through the entire sample preparation and analysis procedure.
- **Matrix Spikes** – One field sample is divided into two or more aliquots. One aliquot is analyzed as is (without spiking), and one or more aliquots are spiked and analyzed. The percent recovery of the known spike is determined. This gives information on the accuracy of the analysis and on the matrix interferences, and provides an indication of the suitability of the method for the matrix.
- **Matrix Spike Duplicates** – When a field sample is divided into three aliquots and two aliquots are spiked, the analysis results provide information on analytical precision, as well as accuracy and matrix interferences.

- **Surrogate Spikes** – Samples undergoing organics analyses are routinely surrogate-spiked with a series of compounds with similar structures to or properties of the components of interest. It is anticipated that these compounds assess the behavior of actual components in individual program samples during the entire preparative and analysis scheme and provide information on analytical accuracy and matrix interferences.
- **Control Charts** – Control charts provide a means of defining acceptable levels of analytical performance and determining whether those levels are achieved and maintained.

The specific analytical methods will be reviewed to determine which QC measures and acceptance criteria are appropriate. Table 12-2 cites frequency of use for the most widely used QC checks.

Table 12-2. Analytical QC Measures and Frequency

QC Measure	Frequency
Method Blank	Each sample set or one every 20 regular samples.
Calibration Check Sample	Daily.
Replicate Sample and Spiked Sample	Each sample set or one every 20 regular samples.
Laboratory Control Sample	Each sample set or one every 20 regular samples.
Surrogate Spike (Organics Analyses)	Each sample.

Note: These QC measures and frequencies apply to each measurement method in use.

Procedures and formulas for calculating applicable QC statistics are given in Section 21. Data validation procedures and acceptance criteria for QC samples are provided in Section 20.

Analytical data from subcontractor laboratories will be validated under the direction of the Work Order QA Manager or the Analytical Services Coordinator. If QC samples are determined to be consistently outside of acceptance limits, every effort will be made to isolate the problem and determine its root cause. Immediate steps will be taken by the Work Order QA Manager to correct or minimize the problem so that the data validity is not endangered.

The laboratory SOW will include audits and corrective actions to help ensure that the maximum amounts of valid data are obtained (see ASP [Appendix B of the QMP]). If a deficiency is detected during the auditing or data validation process, immediate steps will be taken to correct or minimize the problem so that data validity is maintained. Additional information on corrective actions and documentation is provided in Section 18.5.

13. INSTRUMENT AND EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE REQUIREMENTS

The work-order-specific work plans will identify the types of measurement and test equipment (M&TE) to be used to carry out specific fieldwork associated with each work order. The different types of M&TE that may be used during field investigations include, but are not limited to:

- Conductivity, temperature, pH, and redox meters.
- Photo ionization detectors (PIDs).
- Organic vapor analyzers.
- X-ray fluorescent analyzer.
- Personal air monitors.
- Direct-push soil probe.

The Work Order Manager and Field Operations Coordinator/Field Team Leader will determine the specific type and quantity of M&TE needed, as well as a list of anticipated spare parts. Depending on specific work order needs, M&TE will either be rented (and/or leased), purchased, or provided by Parametrix's internal supply of equipment. Equipment purchases will be made in accordance with QPs in the QMP. Equipment rental or leasing will be provided by reputable vendors.

Each work-order-specific QAPP will include procedures for inspection, testing, and maintenance of field M&TE. The work-order-specific QAPP will also include the required frequencies for these activities. Inspection and testing procedures will be performed according to QPs in the QMP. Equipment maintenance will be performed according to manufacturers' specifications by Parametrix or as directed by Parametrix. The frequency of inspection, testing, and maintenance will be established, based on QPs and manufacturers' specifications. The Work Order Manager will assign technical field personnel responsibilities for inspection, testing, and maintenance of M&TE. A hard copy of procedures and manufacturer's specifications will be provided to all field personnel working with the equipment. All equipment will be inspected and tested prior to use.

The results of inspection, testing, and maintenance activities, as well as any problems encountered and any corrective actions, will be documented by Parametrix field personnel in field notebooks. The equipment serial number and date of activity will be included in notebooks so that a complete record is maintained. If problems are encountered, they will be reported to the Work Order QA Manager or the Field Operations Coordinator/Field Team Leader. Corrective actions may include:

- Reinspecting or retesting the equipment.
- Obtaining an alternate or spare equipment item.
- Troubleshooting (according to manufacturers' specifications) to fix the problem (e.g., change batteries, replace parts).
- Returning equipment to the manufacturer for repair.

Training on the use of M&TE will be provided to Parametrix field personnel, as needed. All training and instructions will be documented on site-specific training attendance forms or recorded directly in field notebooks. Following field activities, the field notebooks will be inspected by field personnel for accuracy and will be stored as records in the work order file as described in Section 7.

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14. INSTRUMENT CALIBRATION AND FREQUENCY

The work-order-specific QAPP will identify the specific calibration procedures and the frequency of calibration to be followed when a work assignment requires the collection of samples and/or the performance of analysis involving analytical equipment or measuring devices. These procedures will be specified for all equipment related to the collection of data, either in the field or through laboratory analysis of samples.

The work-order-specific QAPP will contain two calibration sections, one covering field instrumentation and the other covering laboratory equipment. Calibration records specific to each item of equipment will be maintained. Calibration checks or operational checks will be documented in field or laboratory notebooks. The equipment serial number or other ID number will be included in all types of calibration records so that the calibration history can be readily followed. A hard copy of appropriate required calibration procedures will be available to the field and laboratory staff working with the equipment or instrumentation. Areas to be addressed in calibration procedures are listed below.

14.1 FIELD EQUIPMENT

Calibration of M&TE will be performed according to manufacturers' specifications and instructions provided in accompanying operations manuals.

Each manufacturer's instructions should address:

- Calibration procedures and frequency.
- Specified calibration acceptance limits.
- Source of calibration standards and calibration check chemicals/materials.
- Field start-up procedures.
- Field operational checks and frequency.
- Field calibration checks and frequency.
- Routine field maintenance and cleaning procedures.
- Field operations troubleshooting guide.

The results of calibration activities, as well as any problems encountered and any corrective actions, will be documented by Parametrix field personnel in field notebooks. The equipment serial number and date of activity will be included in notebooks so that a complete record is maintained. If problems are encountered, they will be reported to the Work Order QA Manager or the Field Operations Coordinator/Field Team Leader. Corrective actions may include:

- Recalibrating the equipment.
- Obtaining an alternate or spare equipment item.
- Troubleshooting (according to manufacturers' specifications) to fix the problem (e.g., change batteries, replace parts).
- Returning equipment to the manufacturer for repair.

Following field activities, the field notebooks will be inspected by field personnel for accuracy and will be stored as records in the work order file as described in Section 7.

14.2 LABORATORY EQUIPMENT

Required laboratory equipment, calibration and other procedures are to be included in the subcontractor laboratory SOW. When analyses are to be performed by subcontractor laboratories, the laboratory must supply calibration procedures for the analytical instrumentation anticipated to be used. This documentation should address, but may not be limited to:

- Calibration procedure and frequency.
- Acceptance limits for calibration.
- Source and purity of calibration standards.
- Number of points used in generation of standard curve or response factors.
- Calibration checks and frequency.
- Criteria for determining if the instrument is still properly calibrated and corrective action procedures if the criteria are not met.
- Records control requirements.

Additional procedures, checks, and requirements may be submitted by the laboratory, depending on the parameters to be analyzed and the complexity of the methods employed. Calibration records will be maintained by the laboratory for a period of time as specified in the QAPP and the laboratory SOW. If required by the QAPP and the laboratory SOW, the laboratory will provide a hard copy or electronic copy of the calibration records. These calibration records will be included in the work order file as described in Section 7. If required by the work-order-specific QAPP and the laboratory SOW, calibration check samples will be included in the QC data package from the laboratory. Procedures for validating QC samples are included in Section 20, and corrective actions are addressed in Section 12 and in the ASP (Appendix B of the QMP).

15. INSPECTION/ACCEPTANCE REQUIREMENTS FOR SUPPLIES AND CONSUMABLES

Work-order-specific QAPPs will include procedures for inspecting and documenting the conditions of supplies and consumables that may directly or indirectly affect the quality of the task. Typical examples include sample bottles, calibration solutions, reagents, materials for decontamination, and deionized water. The objectives are to enable project personnel to 1) verify, prior to use, that critical supplies and consumables meet specific task quality objectives; and 2) ensure that supplies and consumables that have not been tested, have expired, or that do not meet acceptance criteria, are not used for the task.

Critical supplies and consumables will contain labels with the following information:

- Unique identification number.
- Date received.
- Date opened.
- Date tested (if applicable).
- Date to be retested (if applicable).
- Expiration date.
- Required storage conditions.

Critical supplies and consumables will be inspected by work order personnel prior to use to ensure that they have been properly stored and that they meet acceptance criteria (e.g., expiration date, purity). Any deficiencies will be reported to the Work Order QA Manager or the Work Order Manager so that new supplies can be obtained. The work-order-specific QAPP will list any special acceptance criteria. If special requirements are needed for supplies or consumables, a clear agreement will be established with the supplier. The condition of critical supplies and consumables will be tracked and documented. An example tracking log is shown in Table 15-1. This tracking log will be maintained as a record in the work order file, as described in Section 7.

Table 15-1. Example of a Log for Tracking Supplies and Consumables

Critical Supplies and Consumables (Type, ID No.)	Date Received	Meets Inspection/Acceptance Criteria (Y/N, include date)	Requires Retesting (Y/N, If Yes, include date)	Expiration Date	Comments	Initials/ Date

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16. NON-DIRECT MEASUREMENTS

Each work-order-specific QAPP will identify data that will be obtained from non-direct sources, such as previously collected information in historic databases. These types of data are considered to be “non-direct measurements” because they are not actually generated (through sampling and analysis) as part of the work order and therefore may not have the same level of quality. The work-order-specific QAPP will document the rationale for using previously collected data in terms of supporting the DQOs. In addition, the QAPP will establish evaluation and acceptance criteria for the previously collected data. Acceptance criteria will be established on a work order basis to be consistent with achieving DQOs and DQIs. The work-order-specific QAPP will include qualitative criteria for literature files. For example, literature references should be peer reviewed by recognized experts or reputable professional organizations. The QAPP will also specify qualitative and quantitative criteria for previously collected data. The following evaluation criteria may be used to determine the usability of previously collected data:

- **Comparability** – Check comparability between data collected directly and non-directly in terms of sampling methods, analytical methods, holding times, preservation methods, units, and sample reporting limits (i.e., sensitivity).
- **Data Qualifiers** – Review the non-direct data set to determine if it has been validated and if qualifiers have been assigned to the data in a manner consistent with the procedures in the work-order-specific QAPP.
- **Accuracy and Bias** – If available, review matrix spike QC data from non-direct field and laboratory measurements. Compare to criteria established in the work-order-specific QAPP.
- **Precision** – If available, review duplicate QC data from non-direct field and laboratory measurements. Compare to criteria established in the work-order-specific QAPP.
- **Representativeness** – Check data collected non-directly for potentially confounding effects with other data, such as season, time of day, sample depth, etc.
- **Summarization** – If available, review data reports and validation memoranda for non-direct data sources to assess overall compatibility, usability, and consistency with work order DQOs.

Data from non-direct sources will be evaluated by the Work Order QA Manager, according to these procedures, prior to the data being used in analyses or in data reports. The QA section of data reports (see the QAPP Section 21.3) will include a discussion concerning the limitations on the use of non-direct sources of data and the nature of the uncertainties.

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17. DATA MANAGEMENT

This section describes the basic data management process, tracking the path of the data from generation to final use and storage. This section also includes procedures for storing, retrieving, and final disposition of data. Control mechanisms for detecting and correcting errors and preventing loss of data are also included.

General procedures for data management, with particular emphasis on environmental field samples, are described below. The specific details of the data management system will depend on the uses and needs for the data and should be developed concurrently with DQO planning and be included in the work-order-specific QAPP. The basic steps involved in data management are shown in Figure 17-1 and described below.

17.1 MANAGEMENT OF FIELD DATA

Field data management, including sample identification, chain of custody, sample tracking, data handling, and data reporting, will be provided in the work-order-specific QAPPs and the TSOPs governing fieldwork. Examples of sample documentation, including COC/TR forms and sample container labels, are shown in Attachment 1 of the QAPP. Sample information, including sample identification number, matrix sampled, analysis turnaround time, sample preservative method, station location, sample collection date/time, and COC record, is inserted electronically by field personnel. A hard-copy of the COC/TR form accompanies each sample shipment to the laboratory. The information is then loaded into the laboratory's information management system to automate the sample login process.

Field data (e.g., pH, water level, field notes) will be recorded in bound notebooks or individual sampling data sheets. Examples of sampling data sheets for soil, stormwater, and groundwater are shown in Attachment 1. The sample data sheet can be used as a hard copy or an electronic copy where data are entered into a portable laptop computer. Field personnel will review all field-generated documentation for completeness prior to submittal.

17.2 MANAGEMENT OF LABORATORY DATA

In most cases, the laboratory will be required to provide analytical results and QC data electronically, typically in Microsoft® Excel spreadsheets. The electronic reporting format and the data required for the laboratory QC package (e.g., method blank, matrix spike, laboratory control sample, and surrogate spike) will be specified by Parametrix in the work-order-specific QAPP and in the laboratory SOW. The laboratory electronic data will include data qualifiers resulting from the laboratory's own QC process. Parametrix may request hard copies of other laboratory data, such as instrument calibration, chromatograms, mass spectra, procedural logs for each instrument, sample preparation and extraction logs, and standard preparation logs for purposes of data validation and record storage. The laboratory will also maintain its own records of all data results, laboratory QC, instrument output, extraction logs, etc. for a period of time specified in the laboratory SOW.

The integrity of laboratory data packages will be maintained through the use of a data tracking system. Data validation personnel are required to sign a data tracking sheet upon receipt and, when they relinquish the data package, to maintain a clear chain of custody until the data package is filed as a record in the work order file.

17.3 DATA STORAGE, RETRIEVAL, AND ANALYSIS OF ELECTRONIC MEDIA

All data will be stored in an electronic, work-order-specific database. A database may be in the form of a simple, electronic Microsoft Excel spreadsheet, or in a more complex Microsoft Access database. The specific software choice and format for the database will be determined by the Work Order Manager and the Database Manager in consultation with the client, and will be specified in the work-order-specific QAPP. Laboratory analytical results and QC data will be added to the database by direct transfer of information from computer storage media supplied by the laboratory. The laboratory file will contain data related to the analytical test results, including the value, units, data qualifiers, analytical method, date analyzed, and other information. The database will also include all of the electronic information provided for each sample. Field data (e.g., pH, specific conductivity, dissolved oxygen, turbidity) will be added from the monitoring notebook or sampling data sheets by direct data entry, or electronically, if data were recorded into a field laptop computer.

The Database Manager will be responsible for:

- Obtaining analytical data results and QC data from the testing laboratory in electronic format on computer storage media.
- Comparing electronic data to COC/TR forms to ensure proper transmittal of data results.
- Ensuring, with the Work Order QA Manager, that internal data validation checks are performed on the data and that data validation qualifiers have been assigned to data in the database.
- Creating field data files and entering information from monitoring notebooks or sampling data sheets (e.g., field parameters such as pH and water level).
- Generating data summary tables and spot-checking 10 percent against original files to check for errors. If errors are found, 100 percent of the data will be checked and corrected as needed.
- Assisting other technical staff with outputting data for required analyses such as statistical evaluation.

The electronic database will be stored in a central network location that will be accessible via staff-specific authorization. Only authorized project personnel will be given access rights. The database will be backed up to a secure network on a daily basis to prevent loss of information.

To export data for use with other software tools, data will be extracted from the project database by making queries. The file will then be exported into a neutral format (e.g., delimited ASCII) or to a format that is specific to the analysis tool. Specific analysis tools, as well as performance/acceptance requirements, will be provided in the work-order-specific QAPP. The results of data analyses will be included in work order deliverables, such as data reports, RI/FS reports, risk assessment studies, treatability studies, etc.

Procedures for controlling computer hardware and software to ensure proper operation and compatibility are provided in QP 4.1 of the QMP. These procedures apply to commercially purchased computer hardware and software applications used to design environmental systems or perform computations or database operations on environmental data. The Parametrix Information Technology Division (ITD) is responsible for establishing hardware, software, and configuration standards, for testing hardware/software configurations for proper operation, and for maintaining all Parametrix computer systems. The Database Manager or

computer user is responsible for checking the accuracy of user-generated formulas and computations. When the Database Manager or computer user is writing formulas to perform calculations, an alternate calculation method (e.g., hand-held calculator) will be used initially to verify the accuracy of the formulas.

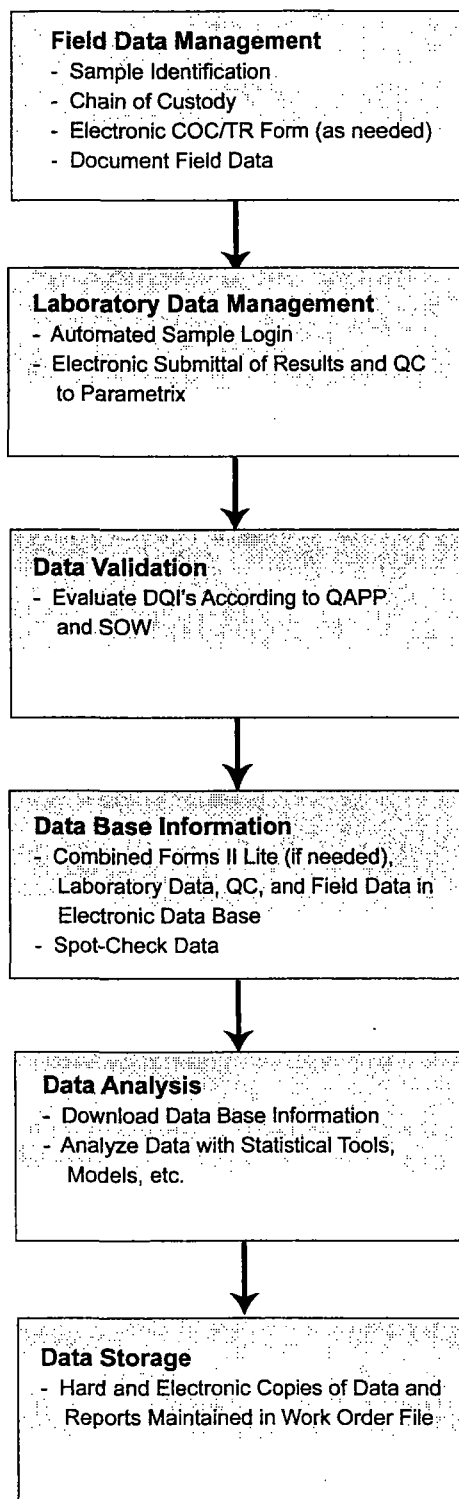


Figure 17-1. Data Management and Data Tracking

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18. ASSESSMENTS AND RESPONSES

Assessments are a learning process intended to increase the user's understanding of the program or system being assessed and to provide a basis for improving such programs or systems. The purpose of assessments is to improve the quality of work by comparing the system or element to the specified requirements. Assessments are conducted at least annually for the corporate and contract levels.

Response refers to the actions taken by the assessed organization as a result of the assessment. Typically, responses involve corrective actions to address deficiencies identified in the assessment. The following sections identify and describe the two major assessment types, management and technical; not all are applicable to each work order. The applicable assessment types will be specified in the work-order-specific work plan or the QAPP. The Project/Deputy Project Manager, Work Order Manager, or Work Order QA Manager may specify additional assessments, as necessary, to ensure that the quality of work meets Client expectations.

18.1 MANAGEMENT ASSESSMENTS

Management assessments evaluate the effectiveness of the QA system and its implementation. These assessments include self-assessments and independent assessments as described below. QP 6.1 covers this topic in greater detail.

18.1.1 Management Self-Assessment

A management self-assessment is the qualitative assessment of a particular program, project, or organization by those immediately responsible for overseeing and/or performing the work. This assessment establishes whether the prevailing quality management structure, policy, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained.

18.1.1.1 Management Systems Reviews

Management systems reviews are self-assessments conducted at the contract level by the QA Officer to establish whether the quality management structure, policies, and procedures are adequate to ensure quality data.

The primary focus of the management systems review is improving performance through:

- Fostering individual ownership of the quality program by increasing employee involvement in quality.
- Encouraging employees to routinely identify opportunities for quality improvement.
- Meeting with the Project Manager, Deputy Project Manager, Work Order Managers, Work Order QA Managers, and technical staff to solicit specific suggestions to improve quality, such as more practical implementation methods, procedural modifications, etc.
- Training the Project Manager, Deputy Project Manager, Work Order Managers, Work Order QA Managers, and technical staff on quality issues and requirements.
- Communicating lessons learned from other management systems reviews.
- Checking on implementation and effectiveness of the quality program for the contract.

The results of the management systems review are reported in a brief memorandum written by the QA Officer and communicated to the COO and Project/Deputy Project Manager.

18.1.2 Independent Management Assessments

An independent management assessment is the qualitative assessment of a program and/or organization by someone other than the group performing the work to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained. The purpose of the management independent assessment is to determine and take necessary response actions regarding:

- Effectiveness of the system of management controls that are established to achieve and ensure quality.
- Adequacy of resources and personnel provided to achieve and ensure quality in all activities.

Independent management assessments are conducted at the corporate level and the contract level. The Parametrix internal Quality Committee (a corporate policy body that supports the Parametrix Quality Program) performs the corporate level assessment. At the contract and work order levels, these assessments are performed by other Parametrix QA staff, who are independent of the work order being assessed. The results of the independent management assessments are reported in a brief memorandum written by the QA Officer and communicated to the COO, Project Manager, and Deputy Project Manager.

18.2 TECHNICAL ASSESSMENTS

Technical assessments assess the qualitative and/or quantitative aspects of a work order work assignment to measure the performance or effectiveness of the technical system with respect to documented requirements. Both self-assessments and independent technical assessments are conducted.

18.2.1 Technical Self-Assessments

Technical self-assessments are conducted as part of a work order by the technical or management staff associated with the work order. Technical self-assessment techniques used include:

- Calculation checking.
- Data quality assessments (DQAs), discussed in more detail in Section 19.
- Data validations, discussed in more detail in Section 20.
- Data report QA sections, discussed in more detail in Section 21.
- Work order self-assessments.

18.2.1.1 Calculation Checking

Mathematical calculations performed on environmental measurements or design calculations must be independently checked periodically. The person performing the check must be technically capable of performing the calculations independently.

18.2.1.2 Data Quality Assessments

The quality of data used to characterize environmental processes and conditions must meet the intended use of the data. Each QAPP will include or reference data reduction, validation, and reporting procedures to ensure that QAPP data quality requirements are met. Data validation is performed to assess the data; data report QA sections assess the reported results and the quality achieved and discuss the adherence to the governing documents. Both are addressed in detail in other sections of this QAPP.

18.2.1.3 Work Order Self-Assessments

Work order self-assessments are evaluations of work order activities conducted by project personnel knowledgeable in the project requirements to determine if the technical requirements are being met. They are intended to provide rapid feedback to the project staff to facilitate timely corrective action. The Project/Deputy Project Manager selects work or activities for project self-assessments as well as the personnel to conduct them, and coordinates with the QA Officer for scheduling. Project self-assessments are conducted using a checklist. A brief report, which may simply be the completed checklist listing both positive observations and deficiencies, is issued by the Work Order QA Manager and is then communicated to the Project Manager, Deputy Project Manager, QA Officer, Work Order Manager.

The responsibilities and procedures for planning, preparing, conducting, reporting, and follow-up for project self-assessments are discussed in QP 7.1.

18.2.2 Technical Independent Assessments

A technical independent assessment is an evaluation process, performed by Parametrix technical staff independent of the work order being assessed, to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications, requirements, and objectives. The purpose of all assessments is to improve the quality of work through identification of potential problems and deficiencies. Assessments may include qualitative or quantitative evaluations. Technical independent assessments include:

- Technical document review.
- Performance audits.
- Field and laboratory audits.
- Field and laboratory surveillance.
- Inspections.
- External audits.

For independent technical assessments conducted by Parametrix, the Work Order QA Manager will issue a brief report summarizing the assessment findings and communicate this report to the Parametrix Project Manager, Deputy Project Manager, QA Officer, and Work Order Manager.

18.2.2.1 Technical Document Review

Technical document review refers to a recorded critical review of work by one or more qualified reviewers independent of the document being reviewed. The review is performed to ensure applicability, technical accuracy, accomplishment of work order objectives, and

conformance to established requirements. Review procedures, responsibilities, and documentation requirements are specified in QP 3.2.

18.2.2.2 Performance Audits

Performance audits are quantitative checks on different segments of work order activity; they are most appropriate to sampling, field measurements, and laboratory analysis activities. Performance audit techniques include checks on sampling equipment volume measurements and the blind analysis of laboratory reference samples (see ASP, Appendix B of QMP). Results are compared to known values to evaluate performance.

18.2.2.3 Field and Laboratory Audits

Authorized technical staff independent of the activities audited conduct field and laboratory audits on work order activities. Auditors for field activities and laboratory operations require technical expertise specific to the activity audited and must be authorized by the QA Officer. Their technical competence is necessary to determine if the technical work order activities observed are following the documented procedures and requirements. The responsibilities and procedures for planning, conducting, and closing out audits are specified in QP 6.2.

18.2.2.4 Field and Laboratory Surveillance

Field and laboratory surveillance is an assessment of processes or activities, conducted by an authorized auditor to verify conformance to specified requirements. Surveillance is similar to an audit, but is intended to be more immediate in providing feedback to the surveyed party. A written plan is not required, and the report is less formal than an audit report. The responsibilities and procedures for planning, conducting, reporting, and closing out surveillances are specified in QP 6.3.

18.2.2.5 Inspections

An inspection is an examination or measurement of an item to determine if it conforms to a specified requirement. Technically qualified personnel, other than those who performed or directly supervised work on the item, perform inspections. QP 5.3 specifies the procedures, responsibilities, and documentation requirements for inspections.

18.2.2.6 External Audits

External audits are audits of Parametrix work performed by, or commissioned by, the Client or regulatory agency with primary oversight responsibilities. It is Parametrix's policy to cooperate fully with external auditors. Parametrix considers it a benefit to be audited, in that such audits may make management aware of deficiencies that might otherwise be overlooked.

Personnel involved with the work should be available during the audit. All files and other related material should be well organized so that required documentation can be located during the audit. As appropriate, the Work Order QA Managers and/or the QA Officer will assist with audit preparation and will participate during the audit.

18.3 FREQUENCY OF INDEPENDENT ASSESSMENTS

The frequency and types of assessments are based on the nature and duration of the work order work. Table 18-1 presents the minimum frequency for each type of independent assessment. The Work Order Managers may request that a work order be audited, but may not prevent the QA Officer from selecting a work order for audit.

Table 18-1. Assessment Frequency

Assessment Type	Minimum Frequency
Self Assessments	
Management Systems Review	One per year.
Calculation Checking	All calculations.
Data Validation	As prescribed in the QAPP.
Data Report QA Section	Every measurement report.
Project Self-Assessment	As determined by Project/Deputy Project Manager.
Independent Assessments	
Technical Review Committee	As determined by Project/Deputy Project Manager.
Technical Review	Every document containing technical information.
Management Assessment	One per year.
Work Order Audit	One per year.
Performance Audit	As required.
Field Audit:	
• Sample Collection/Field Measurements	One per five weeks of field work order.
• Field Oversight with Split Sampling	As determined by QA Officer.
• Field Oversight of Construction	As determined by QA Officer.
Laboratory Audit or Surveillance:	
• Subcontractor Lab	One per year.

18.4 RESPONSE TO ASSESSMENTS

18.4.1 Purpose of Assessments

Assessments are a learning process intended to increase the user's understanding of the program or system being assessed and to provide a basis for improving such programs or systems. Assessments identify noteworthy practices and accomplishments and areas where improvement is required. To bring about improvement, management and staff must respond to assessment findings in a timely manner. When conditions needing corrective action are identified, the responsible person will identify the corrective action and implement it promptly.

18.4.2 Responses to Different Types of Assessments

Depending on the type of assessment, different types of responses are required, ranging from an immediate correction to a detailed investigation into a programmatic cause, followed by extensive corrective action plans and implementation schedules. The following sections describe responses that are appropriate or required for various types of assessments.

18.4.2.1 Management Systems Reviews

Part of the management systems review is a meeting among the work order staff and the QA Officer. This meeting emphasizes the interactive exchange of concerns and suggestions to improve the quality program. Suggestions received by the QA Officer are considered and, if

viable and beneficial, are implemented by the Work Order QA Manager. Suggestions for revisions to the QAPP, including QPs, will be considered immediately, but will usually be retained until a planned revision of the QAPP. Suggestions relevant to other operating groups are forwarded to the managers of those groups. The QA Officer makes suggestions, which are discussed, then management takes appropriate action. The QA Officer documents the responses in a brief memo to the work order staff.

18.4.2.2 Management Assessment of the QA Program

Management assessment findings and recommendations are reported to the COO and Project Manager/Deputy Project Manager. They review the report and discuss its recommendations with the QA Officer, who distributes the report to senior management. The COO and Project Manager/Deputy Project Manager, in consultation with the QA Officer, evaluate the recommendations in terms of benefit, resource requirements, ability to implement, impact on the firm, unintended consequences, and schedules for implementation. They determine the final response and assign responsibilities and implementation schedules as necessary.

18.4.2.3 Technical Self-Assessments

Discrepancies identified by calculation checking are discussed by the originator and the checker and are resolved to technical correctness, if possible. If resolution cannot be reached, the Work Order Manager or designee works to resolve the discrepancy.

DQA Screens Data for Acceptability. Data may be accepted, rejected, or qualified. The response to rejected or qualified data may include re-analysis or resampling as determined by the Work Order Manager, based on DQOs and laboratory SOW for the work.

Technical document review typically results in comments on the draft document that require resolution before the document can be issued. The author, the Work Order Manager, and the reviewer interact as necessary to resolve comments. If resolution cannot be reached, the Project/Deputy Project Manager is contacted to provide resolution. The technical reviewer may require a follow-up review to verify that review comments have been adequately addressed. The issued document is the final response to the technical review. QP 3.2 specifies the procedural steps required for response to technical review comments.

18.4.2.4 Audits and Surveillance

Deficiencies identified in audits require specific responses. Many deficiencies can be corrected quickly. Rapid correction is preferred, whenever possible, because of the immediate benefit to the work order activities. Rapid corrective action is most applicable to isolated mistakes, equipment malfunctions, and deficiencies that are easily corrected. Satisfactory corrective actions performed during an audit, which can be verified by the auditor before the audit report is issued, are considered rapid. The deficiency and corrective action taken are discussed in the audit report. For deficiencies that cannot be corrected rapidly, the auditor should identify the need for corrective action through the use of a CAR form. This form is sent to the Work Order QA Manager for:

- Determination if the deficiency is a significant condition adverse to quality.
- Assignment of responsibility for the response.
- Assignment of a required response date.

The person identified by the Work Order QA Manager must provide a satisfactory response by the required date. A satisfactory response may be evidence that the corrective action has been implemented and appropriate actions have been taken to prevent recurrence, or a plan of

action with specific activities and dates for completion. The Work Order QA Manager is responsible for determining the acceptability of the response. If a satisfactory response is not received shortly after the required date, the CAR is reissued to the QA Officer for action. Further discussion of the corrective action system is located in Section 18.5 and QP 8.1, "Corrective Action."

18.5 CORRECTIVE ACTION SYSTEM

Perhaps the single most important part of any QA program is a well-defined policy for correcting quality problems. Parametrix maintains a closed-loop corrective action system under the direction of the Parametrix QA Officer, with full management support. While the entire QA program operates to prevent problems, it also serves to identify and correct those that may exist.

Corrective actions are required when an item, condition, or situation detrimental to quality is identified. This may include deviation from prescribed methods, items exceeding predetermined acceptability limits, or failure to meet performance requirements or data quality objectives. Anyone that finds a problem is responsible for reporting it. During routine activities, the majority of corrective actions can be implemented immediately by the work order staff and documented in work order notebooks. If the condition is not quickly corrected, the individual initiates a CAR form. The QA Officer can authorize the Work Order QA Managers to process CAR forms and evaluate and accept corrective actions. CAR forms are sent to the Work Order Managers, who assign responsibility for the corrective action and the required timing for the response. The Work Order QA Managers are responsible for tracking, reviewing, accepting, and verifying corrective actions. QP 8.1 describes the responsibilities and procedures associated with corrective actions.

The QA Officer maintains a CAR log that documents the date each CAR was initiated, identifies the originator, briefly cites the problem, and lists follow-up and completion dates.

18.5.1 Organizational Corrective Action

The individual or group who identifies the need for organizational corrective action informs the Work Order QA Managers or the QA Officer. The QA Officer may meet with this group to discuss the situation and potential action. If appropriate, a task force is appointed by the QA Officer to study the situation and recommend the corrective action to be taken.

The recommendations of the task force are submitted to the QA Officer and COO in a confidential report for review and approval. If approved, the corrective action is implemented firm-wide.

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19. DATA REVIEW, VALIDATION, AND VERIFICATION REQUIREMENTS

Data review may be required for certain work orders. The overall objective of a data review is to ensure that all steps of the data review process are appropriate to the needs of the specific work order. Data review may involve several steps, including:

- Validation:
 - Determining the validity of data within its stated objectives or preapproved, standardized criteria.
 - Determining the validity of data for the objectives of a work order.
- Classification:
 - Identifying different types of data.
 - Grouping similar data.
 - Determining what types of data are important to the work assignment.
- Extraction:
 - Extracting and summarizing data specifically pertinent to the work order.
 - Preparing abstracts of selected reports and documents.

Not all of these steps will be required necessarily for all data sets. Further, not all these steps must proceed in the order listed. Newly generated data will require internal technical review to ensure that they are valid data before they are grouped, evaluated, and reported with other data. Data reviewers should also check on the validity of existing data before starting the review process.

Field sampling data will be validated under the direction of the Work Order QA Manager using the following criteria:

- Adherence to an approved sample collection procedure.
- Cleanliness of sampling equipment and containers.
- Collection of required QC samples.

Analytical data from subcontractor laboratories will be validated under the direction of the Work Order QA Manager or the Analytical Services Coordinator using, as criteria, the acceptance limits specified in the work-order-specific QAPP and the subcontractor laboratory SOW for some or all of the following:

- Blank samples.
- Duplicate samples.
- Calibration check samples.
- Matrix spike/matrix spike duplicate samples.
- Surrogate compounds.
- Spiked samples.

- Rinsate samples.
- Audit samples.

Validation procedures and criteria for accepting, rejecting, and qualifying data are discussed in more detail in the next section.

Data classification and extraction will require an informed, technical judgment to define the types of data deemed important to the work order and, after the data have been extracted, to identify major and minor issues to be resolved within the data. The extraction of data lends itself to QC measures, such as checklists and summary forms, to ensure the completeness and comparability of data.

20. VALIDATION AND VERIFICATION METHODS

This section discusses validation and verification techniques to ensure that data are valid and useable. Validation of analytical data from subcontractor laboratories will be performed by trained, experienced Parametrix personnel under the direction of the Work Order QA Manager or the Analytical Services Coordinator. Determining quality and usability will include, but will not be limited to, such factors as sampling methods, sample preparation, analytical methods, QC, and documentation. Data validation requirements will depend on the methods used by the laboratory. Criteria will differ between data generated by subcontractor laboratories, as explained below.

20.1 DATA VALIDATION REQUIREMENTS FOR DATA GENERATED

Parametrix staff will only be responsible for validation of data generated by subcontractor laboratories.

20.2 DATA VALIDATION REQUIREMENTS FOR DATA GENERATED BY SUBCONTRACTOR LABORATORIES

Parametrix will use the techniques described in this section to evaluate the acceptability of data generated by subcontractor laboratories. These techniques, along with specific data acceptance criteria, will be included in the work-order-specific QAPP and the laboratory SOW, as described in the ASP (Appendix B of the QMP). Data will be evaluated against acceptance criteria for DQIs developed during the DQO process. Acceptance criteria will be based on:

- Fulfilling DQOs.
- Meeting QC acceptance criteria established in the specific analytical methods.
- Meeting QC acceptance criteria established in EPA validation guidance.

Analyses conducted by subcontractor laboratories can include all media (groundwater, surface water, soil, subsurface soil, sediment, etc.) and all types of analyses (organic, inorganic, wet chemistry, radiochemical, explosives, etc.). Validation of subcontractor-generated data will be conducted and will include evaluation of some or all of the following:

- Completeness of data package and inspection of COC/TR forms.
- Sample holding times, as specified by the analytical method.
- Performance of initial and continuing calibration, as specified in the work-order-specific QAPP and SOW.
- Laboratory quality, control samples (matrix spike/matrix spike duplicates [MS/MSDs], analytical replicates, method blanks, surrogates), and other laboratory QC checks, as appropriate, and as specified in the individual work-order-specific QAPPs and SOWs.
- Correct identification of analytes.
- At least a 10 percent check of calculations performed (100 percent if errors are found), unless the work-order-specific QAPP specifies otherwise.
- Potential contamination of field blanks.

- Evaluation of field QC duplicates, field spikes, and field splits, etc., where appropriate, against criteria specified in the work-order-specific QAPP.

Laboratory data generated to fulfill the Work Order, will meet, at a minimum, the QC data requirements specified in the standard method used or in the SOPs developed for the work-order-specific QAPP.

Data validation results will be summarized by sample matrix or analysis type (i.e., organics, inorganics, conventionals, etc.) in technical memoranda. Data qualifiers will be applied based on the reviewer's judgment and experience and consulting EPA laboratory guidelines. Potential qualifiers applied will include:

- "U" – The analyte was analyzed for, but was not detected above the level of the reported sample quantitation limit.
- "J" – The result is an estimated quantity. The associated numerical value is the approximate concentration of the analyte in the sample.
- "N" – The analysis indicates the presence of an analyte for which there is presumptive evidence to make a "tentative identification."
- "NJ" – The analysis indicates the presence of an analyte that has been "tentatively identified", and the associated numerical value represents its approximate concentration.
- "UJ" – The analyte was analyzed for, but was not detected. The reported quantitation limit is approximate and may be inaccurate or imprecise.
- "R" – The data are unusable. The sample results are rejected due to serious deficiencies in meeting QC criteria. The analyte may or may not be present in the sample.

A summary table outlining all qualified data will be included with all data validation memoranda. Data validation memoranda will be included in the QC sections of data reports and other data deliverables.

21. RECONCILIATION WITH DATA QUALITY OBJECTIVES

Once generated data have been reviewed, verified, and/or validated, the Work Order QA Manager will evaluate the finalized sample data packages against the DQOs in the work-order-specific QAPP. The DQOs will have specified the quantitative and qualitative goals to be achieved. As discussed in Section 5, each work-order-specific QAPP will define the DQOs and DQIs, which are defined in terms of precision, accuracy, bias, sensitivity, representativeness, completeness, and comparability.

Although each work-order-specific QAPP will include these parameters, this QAPP discusses each DQI parameter below. In Section 21.2, DQA will be discussed as a QA tool to determine if data are of the right type, quality, and quantity to support their intended use. Section 21.3 discusses QA sections to be included in data reports.

21.1 DQI DEFINITION AND EVALUATION

The principal indicators of data quality are precision, accuracy, bias, sensitivity, completeness, representativeness, and comparability. These DQIs are described individually below.

Precision is the agreement between a set of replicate or duplicate measurements without assumption of knowledge of the true value. Precision is assessed by means of duplicate/replicate sample analysis. Precision can usually be expressed as relative percent difference, %RPD, or relative standard deviation, %RSD. These quantities are defined as follows:

$$\%RPD = 100 \times \frac{|(X1 - X2)|}{[(X1 + X2) \div 2]}$$

Where:

X1 and X2 are the reported analyte concentrations for the parent and duplicate samples.

$$\%RSD = \frac{s}{X} \times 100$$

Where:

“s” is the standard deviation of the series of individual measurements and X is the mean of the series of individual measurements.

Intuitively, it is desirable that, on the average, the reported concentration equals the actual concentration present in a sample.

Ideally, the analytical method should not have any systematic errors. **Accuracy** measures the average or systematic error of a method. Accuracy of a chemical test result is assessed by spiking samples with known standards and establishing the average recovery. For organics analyses, two types of recoveries are measured: matrix spikes and surrogate spikes. For a matrix spike, known amounts of standard compounds, which are identical to the compounds present in the sample of interest, are added to the sample. For a surrogate spike, the standards are chemically similar, but not identical, to the compounds being analyzed in the fraction. The purpose of the surrogate spike is to provide QC on every sample by constantly monitoring for unusual matrix effects and gross sample processing errors. Since accuracy is often determined from spiked samples, laboratories commonly report accuracy in this form.

Percent recovery is defined as:

$$\% \text{ Recovery} = 100 \times R/S$$

Where:

R = reported concentration.

S = spiked concentration.

Accuracy measurements are usually carried out with a minimum frequency of 1 in 20, or one per batch of samples analyzed, under the same sampling episode. Actual accuracy objectives may vary on a site-specific basis.

Bias is the systematic or persistent distortion of a measurement process that causes errors in one direction. Bias may be assessed by using field and laboratory matrix spike samples, similar to the process described for accuracy. Bias measurements are usually carried out with a minimum frequency of 1 in 20, or one per batch of samples analyzed, under the same sampling episode.

Sensitivity expresses the capability of a method or instrument to meet prescribed measurement reporting limits. Sensitivity is assessed by comparing data reporting limits with risk-based reporting limits, analytical or instrument method reporting limits, or laboratory quantitation limits, as appropriate.

Representativeness expresses the degree to which sample data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, or environmental condition. It can also be assessed by comparing the anticipated sample variability with the variability shown in the actual field replicate samples. Field blanks and field duplicates are usually obtained at a minimum of 10 percent for each sampled matrix, or one-per-day frequency. This information is used to assess field and transport contamination and method variation. However, the frequency may vary, depending on the particular requirements associated with the site. Laboratory method blanks will be performed to assess laboratory contamination at a minimum frequency of 5 percent, or one per batch of samples processed at the same time.

Comparability is a qualitative parameter expressing the confidence with which one data set can be compared with another. Sample data should be comparable with other measurement data for similar samples and sample conditions. Comparability of the data will be maintained by using consistent methods and units. The work-order-specific QAPP and the laboratory SOW will list the specific analysis parameters, reporting units, applicable methods for analytes, and target reporting limits. Actual reporting limits will depend on the sample matrix (necessary dilutions, etc.) and will be reported as defined for the specific samples.

Completeness is a measure of the amount of valid data obtained from the analytical measurement system and the complete implementation of defined field procedures. The completeness objective is essentially the same for all data uses: that a sufficient amount of valid data be generated. Parametrix will define the completeness objective for each work order during DQO development. The target completeness objective is usually at least 90 percent.

The criteria and DQIs used for precision and accuracy/bias and determination of sensitivity and completeness will be used to quantitatively compare sample data results with the specific work order DQOs and DQIs. The %RPD, %RSD, and percent recoveries of sample data will be compared with the QAPP DQOs. The qualitative evaluation of comparability and representativeness will also be compared to DQOs and DQIs. Any deviations and/or data

outliers will be discussed with work order and laboratory management to determine possible causes for such conditions and to implement corrective actions. Discussions, evaluations, data limitations, and conclusions, as a result of the above assessments, will be consolidated into the QA section of the data report.

21.2 DATA QUALITY ASSESSMENT APPLICATION

The DQA process is a QA tool to evaluate data to determine if they are of the right type, quality, and quantity to support their intended use. It is built on the fundamental premise that data quality is meaningful only when it relates to the intended use of the data.

As outlined in EPA's Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4, Final, February 2006, the DQA Process involves five steps that begin with a review of the planning documentation and end with answers to the questions posed during the planning phase of the study. The five steps are summarized as follows:

- **Step 1: Review the Project's Objectives and Sampling Design:** Review the objectives defined during systematic planning to ensure that they are still applicable. If objectives have not been developed (e.g., when using existing data independently collected), specify them before evaluating the data for the project objectives. Review the sampling design and data collection documentation for consistency with the project objectives, noting any potential discrepancies.
- **Step 2: Conduct a Preliminary Data Review:** Review QA reports (when possible) for the validation of data, calculate basic statistics, and generate graphs of the data. Use this information to learn about the structure of the data and identify patterns, relationships, or potential anomalies.
- **Step 3: Select the Statistical Method:** Select the appropriate procedures for summarizing and analyzing the data, based on the review of the performance and acceptance criteria associated with the project's objectives, the sampling design, and the preliminary data review. Identify the key underlying assumptions associated with the statistical test.
- **Step 4: Verify the Assumptions of the Statistical Method:** Evaluate whether the underlying assumptions hold, and whether departures are acceptable, given the actual data and other information about the study.
- **Step 5: Draw Conclusions from the Data:** Perform the calculations pertinent to the statistical test, and document the conclusions to be drawn as a result of these calculations. If the design is to be used again, evaluate the performance of the sampling design.

These five steps are presented in a linear sequence, but the process is, by nature, iterative. For example, if the preliminary data review reveals patterns or anomalies in the data set that are inconsistent with the DQOs, then some aspects of the study planning may have to be reconsidered in Step 1. Likewise, if the underlying assumptions of the statistical test are not supported by the data, then previous steps of the DQA Process may have to be revisited. The strength of the process is that it is designed to promote an understanding of how well the data satisfy their intended use by progressing in a logical and efficient manner.

21.3 DATA REPORT QA SECTIONS

Reports that present data resulting from field or laboratory measurements generated by Parametrix or its subconsultants require a QA section that addresses the quality of the data and its limitations. The QA section should be commensurate in size and detail with the data reported. A letter report may have a paragraph QA section, while a Remedial Investigation Report may have a 10- to 20-page QA section.

Each QA section, no matter how brief, should address:

- Adherence to the QAPP. Deviations should be noted and explained, and the potential impact of any significant deviation from the QAPP should be assessed and documented.
- Precision, accuracy, bias, sensitivity, and completeness of the data report, in quantitative terms.

The precision, accuracy, bias, sensitivity, and completeness actually achieved should be compared with the respective DQIs and the MQOs established in the QAPP.

Additional information that should be provided includes, as appropriate:

- Representativeness and comparability of the data in qualitative terms as compared with the DQOs and DQIs set forth in the QAPP.
- Summary of QC activities, including data validation memoranda.
- Summary of QA activities:
 - Results of performance and/or system audits.
 - Description of quality problems found.
 - Description of corrective actions taken.
- Conclusions regarding data limitations or uncertainties.
- Specific information required by the Client.

ATTACHMENT 1

Sample Data Sheets and Chain-of-Custody Forms

Groundwater Sampling Field Data Sheet No. 1

Well #: _____
Sample #: _____

Project Number: _____				Date: _____			
Project Name: _____				Location: _____			
Project Address: _____				Sampled By: _____			
Client Name: _____				Purged By: _____			
Casing Diameter: 2" _____ 4" _____ 6" _____ Other _____							
Depth to Water (feet): _____				Purge Volume Measurement Method: _____			
Depth of Well (feet): _____				Date Purged: _____			
Reference Point (surveyor's notch, etc.): _____				Purge Time (from/to): _____			
Date/Time Sampled: _____							
Purge Volume Calculation: $(\pi^2 h)(7.48 \text{ gal/ft}^3)(\# \text{ Casing volumes})$ Purge Volume (gallons) for: 2" = $(0.16)(h)(\#Cv)$; 4" = $(0.653)(h)(\#Cv)$; 6" = $(1.48)(h)(\#Cv)$ Calculated Purge Volume (gallons): _____ Actual Purge Volume (gallons): _____							
TIME (2400 hr)	CUMULATIVE VOLUME (gal)	pH (units)	Ec ($\mu\text{mhos/cm}$ 25°C)	COLOR (visual)	TURBIDITY (visual)	ODOR	OTHER
_____	_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____	_____
Purge Equipment: _____ Sampling Equipment: _____							
Laboratory: _____				Date Sent to Lab: _____			
Chain-of-Custody (yes/no): _____				Field QC Sample Number: _____			
Shipment Method: _____				Split With (names[s]/organization): _____			
Well Integrity: _____							
Remarks: _____							
Signature: _____							

Sample #: _____

Signature: _____

Sample #: _____

Project Number: _____

Project Name: _____

Project Address: _____

Client Name: _____

Sample Location: _____

Date: _____

Sampled By: _____

Depth of Sample (feet): _____

Date/Time Sampled: _____

Air temperature: _____

Weather Conditions: _____

PID Measurements (ppm): _____

Sample Number: _____

Sampled By: _____

Laboratory: _____

Chain-of-Custody (yes/no): _____

Date Sent to Lab: _____

Shipment Method: _____

Signature: _____

Page ____ of ____

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APPENDIX B

Analytical Services Plan

Appendix B - Draft Analytical Services Plan for Remedium Work Order Revision No. 0

Prepared for

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August 25, 2008

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Revision No. 0. Prepared by Parametrix, Albany, Oregon. August 25, 2008.

APPROVALS

Appendix B Draft Analytical Services Plan for Remedium Work Orders

Prepared for

Remedium Group, Inc.

Parametrix, Brad Hermanson, Quality Assurance Officer

Date

Parametrix, William Stubblefield, Project Manager

Date

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Contract File		Parametrix

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TABLE OF CONTENTS

1. PURPOSE AND OBJECTIVES	B-1
2. PLANNING FOR ANALYTICAL SERVICES	B-1
3. ANALYTICAL LABORATORY PROCUREMENT	B-2
4. ANALYTICAL ACCOUNTABILITY	B-2
4.1 LABORATORY PERFORMANCE AND CORRECTIVE ACTIONS.....	B-2
4.2 PE SAMPLE PROGRAM	B-4
4.3 PE SAMPLE INFORMATION REQUEST FORM.....	B-4
5. FIELD ANALYSIS AND SCREENING EQUIPMENT.....	B-5
6. DATA MANAGEMENT AND REPORTING	B-6

LIST OF FIGURES

B-1 Process of Planning and Procuring Analytical Services	B-7
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ATTACHMENTS

1 Parametrix Performance Evaluation Sample Tracking Form	
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ACRONYMS AND ABBREVIATIONS

ANSETS	Analytical Services Tracking System
DQOs	Data Quality Objectives
M&TE	Measurement and Test Equipment
PE	Performance Evaluation
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QPs	Quality Procedures
SOP	Standard Operating Procedure
SOW	Statement of Work
TSOP	Technical Standard Operating Procedure

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1. PURPOSE AND OBJECTIVES

This Analytical Services Plan describes Parametrix's procedures for planning, procuring, and managing analytical services associated with the execution of each work order issued. Provisions for obtaining routine, nonroutine, special, and rapid turnaround analytical services are included, as well as procedures to audit and monitor the performance of stationary and mobile laboratories. Subcontracting procedures to hold laboratories financially accountable for data that are not valid and/or defensible are also included. The plan also specifies the procedures of Parametrix for the use of field analytical and screening instruments, and for data management and reporting.

The key objectives of this plan are as follows:

- Provide a mechanism for subcontracting non-routine analytical services.
- Establish procedures to ensure the performance and accountability of subcontractors who perform analytical services.
- Specify data management and reporting procedures, including procedures for subcontracted analytical services.

2. PLANNING FOR ANALYTICAL SERVICES

Unless otherwise provided, Parametrix will prepare a site-specific Quality Assurance Project Plan (QAPP). The QAPP will present data quality objectives (DQOs) and the procedures for sampling and analysis in accordance with EPA requirements and guidelines QA/R-5 and QA/G-5, respectively. The QAPP will include relevant technical standard operating procedures (TSOPs) for sample collection, handling, labeling, etc. The QAPP will also detail analytical services requirements and address the analytical parameters, analytical methods, and required turnaround times necessary to meet the project DQOs. The QAPP will also address the appropriate requirements for split sample analysis necessary to produce comparable analytical results.

Based on the site-specific requirements, the Parametrix Analytical Services Coordinator will identify the analytical services process and select the delivery mechanism with the best chance to provide accurate laboratory work at a reasonable cost. In some instances, other, non-routine analytical services may be required. These instances may include:

- Rapid turnaround of analytical services.
- Special analytical services such as analyte speciation, ultra-low detection limits, radionuclides, etc.
- Mobile laboratory services.

Nonroutine analytical services laboratory procurement is described in greater detail in the next section. The process of planning and procuring analytical services is illustrated in Figure 1.

3. ANALYTICAL LABORATORY PROCUREMENT

As defined in work order work plans (if required), Parametrix will procure laboratory analytical services on a site-specific, competitive basis to ensure that such services are obtained at the lowest reasonable prices from qualified analytical laboratories. These procurement procedures apply to both fixed and mobile laboratories. The work-order-specific QAPP will identify the roles and responsibilities of Parametrix, including those of the Analytical Services Coordinator whose responsibilities will include developing the subcontractor laboratory Statement of Work (SOW), coordinating activities, and ensuring analytical accountability.

Parametrix will prepare a laboratory SOW for all analytical-services-related work. The laboratory SOW will include, but not be limited to, sample preparation and analytical methods, laboratory equipment, calibration procedures, chain-of-custody requirements, data deliverable requirements, quality control (QC) requirements, estimated number of samples, turnaround times, packaging and shipping requirements, restrictions, and penalties. The laboratory SOW will be included in the procurement package that will be sent to multiple laboratories for competition.

The SOW will also contain requirements for sample storage and disposal. The subcontractor laboratory will usually be required to maintain possession of environmental samples for no less than 60 days after the delivery and acceptance of the sample data packages by Parametrix. Sample disposal and the disposal of used sample bottles/containers will be the responsibility of the laboratory. Any samples that contain hazardous materials will be disposed in accordance with all applicable laws and regulations governing disposal of such materials. The subcontractor laboratory will be responsible for the proper disposal of any on-site laboratory-generated waste.

Parametrix will conduct a cost and price analysis to determine reasonability of the prices quoted. Emergency situations or lack of competition may require Parametrix to enter into negotiations with subcontractor laboratories. Parametrix is committed to providing the best value in analytical services and sample data packages. All procurements will be performed in accordance with Parametrix procurement policies.

4. ANALYTICAL ACCOUNTABILITY

4.1 LABORATORY PERFORMANCE AND CORRECTIVE ACTIONS

Parametrix will extensively review the credentials of the analytical laboratories before any subcontract is awarded. Laboratories responding to solicitation from Parametrix must provide the following (as requested):

- Evidence that the laboratory is capable of performing EPA, American Society for Testing and Materials, National Institute for Occupational Safety and Health Standard Methods and approved methods including, but not limited to, SW-846, and EPA Series 100 600 methods, as required. This evidence consists of documentation of state certification or National Environmental Laboratory Accreditation Program for the required methods, as well as the results from any other certification or round-robin program(s) in which the laboratory is a participant.
- Résumés of key laboratory technical and managerial personnel.

- A copy of the laboratory's latest quality assurance (QA) plan and applicable standard operating procedures.
- Results from the laboratory's most recent state Department of Health (or equivalent program) performance evaluation (PE) sample analysis within the previous 12 calendar months and, if applicable, evidence of action taken to correct any deficiencies.
- Applicable financial statements to ensure laboratory's financial solvency.
- A copy of the Method Detection Limit Study, if required.
- Evidence that laboratory is currently certified, as required, for parameters of interest.
- A copy of procedures for performing in-house data review and data validation.

This information, in addition to the laboratory's statement of qualifications, data review, and validation procedures, etc., is subject to both technical and QA review by trained, experienced Parametrix staff. Those laboratories that do not meet the requirements of Parametrix will be disqualified from further consideration.

Knowing the specific physical location where analyses are being performed is important in the event that problems occur at a specific laboratory facility. Therefore, subcontractor laboratories will not be permitted to subsequently subcontract out analyses to other independent laboratories or other laboratories within a laboratory chain without prior written approval from Parametrix.

Parametrix subcontracts will contain provisions to ensure subcontractor performance. These provisions include payment penalties for lost or broken samples or failure to meet delivery schedules. Laboratories will be required to follow the prescribed analytical methodologies that call for sample extraction and analysis to be performed within specified time constraints. Also, the laboratory must provide a minimum percentage of data that are determined to be usable based on validation procedures contained in the QAPP and laboratory SOW. Failure to meet these requirements will subject the laboratory to payment reductions and other possible penalties such as termination of the subcontract.

Since the ultimate goal is to have the analytical laboratory perform well, concerted efforts will be made to monitor the subcontractor's progress and to resolve any noted problems quickly. This approach limits impact to the progress of the prime contract work. Routine audits and surveillance by Work Order QA Managers or the Analytical Services Coordinator shall monitor laboratory integrity and accountability. The responsibilities and procedures for planning, conducting, and closing out audits and surveillances are specified in the Quality Management Plan (QMP). Laboratory audits will occur on a frequency of approximately one per year or as specified in the QAPP and the SOW. Parametrix will also conduct data validation to check the quality of the analytical results. Data validation will be conducted using a validation standard operating procedure (SOP) based on the laboratory SOW, analytical methods, and work-order-specific QAPP. Data validation memoranda will detail any noncompliance and summarize the data usability. If a deficiency is detected, every effort will be made to isolate the problem and determine its root cause. Immediate steps will be taken to correct or minimize the problem so that the data validity is not endangered.

The integrity of laboratory data packages will be maintained through the use of a data tracking system. Data validation personnel are required to sign a data tracking sheet upon receipt and when they relinquish the data package to maintain a clear chain-of-custody until

the data package is released to the Project Manager and the full package is delivered to the Client.

As part of the laboratory procurement process, the sample data QC package requirements will be contained in the laboratory SOW and thus included as part of the subcontract agreement with Parametrix. The laboratory SOW, along with the financial penalties, will ensure that the selected laboratory provides sample data QC packages that are complete, valid, and defensible in court.

4.2 PE SAMPLE PROGRAM

Performance audits are quantitative checks on technical activities and proficiency that are most applicable to analytical work. Performance audits may include checks on volumetric measurements and analysis of spiked samples or PE samples. To the extent possible, PE samples will be specific to the analysis requested of the subject laboratories.

PE samples will be submitted to the laboratories on an annual basis or as defined in the applicable analytical method and/or the corresponding analytical SOW. If any of the selected laboratories do not have certification for a parameter group specified in the analytical SOW, then Parametrix may provide a PE sample to the laboratory along with the first set of samples to be analyzed.

Commercially available QC standards and reference standards with known values will be used. Parametrix will define acceptance limits for PE samples based on limits for spiked samples of the same analyte class, when appropriate. Parametrix will submit the PE sample to the laboratory as necessary, or arrangements will be made for direct shipment from the source. If the PE sample is shipped directly to the laboratory, then the certification information will be sent to Parametrix.

The certificate of analysis or list of true values and lot number of the PE samples will be maintained in the work order file along with the Parametrix PE sample tracking form shown in Attachment 1.

During data validation, the results of the PE sample will be compared to the known value and acceptance limits. Results will be tabulated as a percent of acceptable results per analyte class. A report of the PE results will be issued to the laboratory. The PE report will have the results submitted by the laboratory listed against the known value and the acceptable range. The laboratory will have 10 working days from receipt of the report to address and explain any results outside acceptable limits. A follow-up PE sample may be submitted to the laboratory if it is deemed necessary. PE samples will periodically be submitted to the laboratories in order to evaluate performance on an ongoing basis. These samples will be submitted at a rate of one PE sample per analyte class per year.

Request for copies of current PE sample results administered by state and other certification organizations and agencies will be an additional source of input regarding laboratory performance. While initially requested as part of the procurement laboratory selection process, these results will be requested on an ongoing basis from the contracted laboratories.

4.3 PE SAMPLE INFORMATION REQUEST FORM

Standards should be traceable to a primary standard. All PE samples should be accompanied by instructions for preparation prior to analysis. Additional information is required on the PE sample and is shown below. If the PE sample is to be sent directly to the laboratory, then the following information should be sent to Parametrix only:

Expiration Date: _____

Analyte Composition: _____

Analyte(s) Concentration (units): _____

Known Value/Units: _____

Acceptance Range: _____

5. FIELD ANALYSIS AND SCREENING EQUIPMENT

The work order work plans (if required) will identify the types of measurement and test equipment (M&TE) to be used to carry out specific fieldwork associated with each work order. The different types of M&TE that may be used during field investigations include, but are not limited to:

- Conductivity, temperature, pH, and redox meters.
- Photoionization detectors.
- Organic vapor analyzers.
- X-ray fluorescent analyzer.
- Personal air monitors.
- Direct-push soil probe.

The Work Order Manager and Field Operations Coordinator/Field Team Leader will determine the specific type and quantity of M&TE needed, as well as a list of anticipated spare parts. Depending on the specific work order needs, M&TE will either be rented (and/or leased), purchased, or provided by Parametrix's internal supply of equipment. Equipment purchases will be made in accordance with quality procedures (QPs) in the QMP. Equipment rental or leasing will be provided by reputable vendors.

Each work-order-specific QAPP will include procedures for inspection, testing, and maintenance of field M&TE. The work-order-specific QAPP will also include the required frequencies for these activities. Inspection and testing procedures will be performed according to QPs in the QMP. Equipment maintenance will be performed according to manufacturers' specifications by Parametrix or as directed by Parametrix. The frequency of inspection, testing, and maintenance will be established, based on QPs and manufacturers' specifications. The Work Order Manager will assign technical field personnel responsibilities for inspection, testing, and maintenance of M&TE. A hard copy of procedures and manufacturer's specifications will be provided to all field personnel working with the equipment. All equipment will be inspected and tested prior to use.

The results of inspection, testing, and maintenance activities, as well as any problems encountered and corrective actions, will be documented by Parametrix field personnel in field notebooks. The equipment serial number and date of activity will be included in notebooks so that a complete record is maintained. If problems are encountered, they will be reported to the Work Order QA Manager or the Field Operations Coordinator/Field Team Leader. Corrective actions may include:

- Re-inspecting or retesting the equipment.

- Obtaining an alternate or spare equipment item.
- Troubleshooting, according to manufacturer's specifications, to fix the problem (e.g., change batteries, replace parts).
- Returning equipment to the manufacturer for repair.

Training on use of M&TE will be provided to Parametrix field personnel, as needed. All training and instructions will be documented on site-specific training attendance forms or recorded directly in field notebooks. Following field activities, the field notebooks will be inspected by field personnel for accuracy and will be stored as records in the work order file as described in Section 6.

6. DATA MANAGEMENT AND REPORTING

Data management procedures, including sample identification, chain-of-custody, sample tracking, data handling, and data reporting, will be provided in the work-order-specific QAPPs and TSOPs governing fieldwork. Subcontracted Analytical Services Tracking System (ANSETS) data may include field screening, mobile laboratory, and stationary laboratory analyses.

The Analytical Services Coordinator will work in close communication with the analytical laboratories to manage data and assess sampling and laboratory analysis performance. This communication will ensure that any problems associated with sample delivery, sample preparation, analysis, data evaluation, or reporting are addressed and resolved immediately. Communications associated with the sampling, analysis, and reporting process, as well as problems encountered and corrective actions, will be documented and placed as records in the work order files.

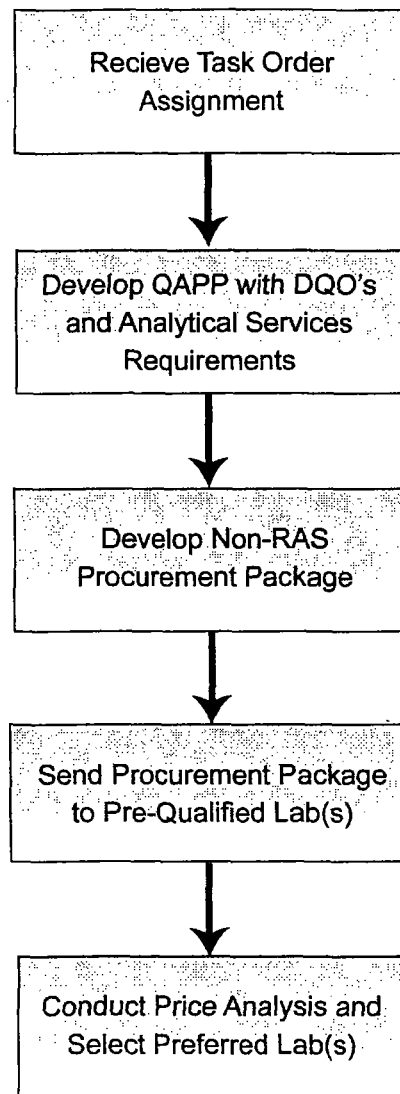


Figure B-1. Process of Planning and Procuring Analytical Services

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ATTACHMENT 1

Parametrix Performance Evaluation Sample Tracking Form

LABORATORY NAME: _____
DATE OF ANALYSIS: _____
LOT NUMBER(S): _____

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